A STUDY TO EVALUATE THE EFFECTIVENESS OF COLD APPLICATION ON LEVEL OF PAIN ASSOCIATED WITH INTRA MUSCULAR IMMUNIZATION AMONG INFANTS IN SELECTED HOSPITAL AT ERNAKULAM

COIMBATORE

A DISSERTATION SUBMITTED TO THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE DEGREE OF

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BY

MARY GEEN

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APPROVED BY THE DISSERTATION COMMITTEE ON…….....

RESEARCH GUIDE ……...……...…….

Prof. Dr. Mrs. R. ANNAPOORANI, MA., M.Phil., Ph.D.,
DSP., D.Sc., (GERMANY)
PROFESSOR IN RESEARCH METHODS,
ANNAI MEENAKSHI COLLEGE OF NURSING,
COIMBATORE.

CLINICAL GUIDE ……..……...…….

Mrs. R. SUTHANTHIRAKUMARI, M.Sc (N).,
ASSOCIATE PROFESSOR,
ANNAI MEENAKSHI COLLEGE OF NURSING,
COIMBATORE.

MEDICAL EXPERT ……...……..

Prof. Dr. S.VEERAKESARI, M.D.,
CONSULTANT PHYSICIAN,
SHRI MEENAKSHI HOSPITAL,
COIMBATORE.

A DISSERTATION SUBMITTED TO THE TAMILNADU
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MASTER OF SCIENCE IN NURSING
OCTOBER 2015

VIVA VOICE

1. INTERNAL EXAMINER…….……..……
2. EXTERNAL EXAMINER…….…….…….……...

This is to certify that the dissertation entitled **"A Study To Evaluate The Effectiveness Of Cold Application On Level Of Pain Associated With Intra-Muscular Immunization Among Infants In Selected Hospitals At Ernakulum"** is a bonafide work done by **Mrs. Mary Geen.**, **Annai Meenakshi College Of Nursing** in partial fulfillment of the university rules and regulation for award of **M.Sc., Nursing Degree Course** under my guidance and supervision during the academic year of **October 2015.**

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NAME & SIGNATURE OF DEAN/PRINCIPAL ……...…….

CERTIFIED THAT THIS IS THE BONAFIDE WORK OF

MARY GEEN

ANNAI MEENAKSHI COLLEGE OF NURSING,

COIMBATORE.

SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT
FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING
TO THE TAMILNADU DR. M.G.R. MEDICAL
UNIVERSITY, CHENNAI.

COLLEGE SEAL:

PROF. MRS. M. MUMTAZ, M.Sc., (N)., MBA (HM)

PRINCIPAL,

ANNAI MEENAKSHI COLLEGE OF NURSING,

COIMBATORE,

TAMILNADU.

DEDICATION

****

"I dedicate this book to

God almighty who blessed me to finish this work successfully."

I dedicate this book for my **Husband & Son**

Mr. MONU VARGHESE & MASTER. ELON

Who made my life purposeful and meaningful

I dedicate this book to my lovable **Parents**

Mr. JACKSON

& Mrs. BEENA JACKSON,

For provided me with best education

I dedicate this book to my beloved **Sister**

Ms. MARY JIFFY

I dedicate this book to my **Mother-in-law**

Mrs. MOLY VARGHESE

For her love and support

****

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ABSTRACT

INTRODUCTION: Pain is highly unpleasant and very personal sensation. Infants have pain during intramuscular immunization. Cold application is a simple procedure to reduce pain due to intramuscular immunization. OBJECTIVE: To evaluate the effectiveness of cold application on level of pain associated with intramuscular immunization. DESIGN: A quantitative approach using quasi- experimental post only test with control group design. PARTICIPANTS: 60 infants undergoing intramuscular immunization. SAMPLING TECHNIQUE: A non-probability purposive sampling technique is used to select samples from Taluk hospital, Ernakulam. INTERVENTION: Cold application is applied for 5 seconds just prior to inserting the needle. TOOLS: Standardized Neonatal Infant Pain Scale is used to assess the level of pain associated with intramuscular immunization. RESULTS: Analysis among Experimental group by using independent 't' test found significant value 9.13 at $p<0.05$ level. CONCLUSION: Cold application is effective on reducing the pain associated with intramuscular immunization among infants.

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CHAPTER-1

INTRODUCTION

"We find delight in the beauty and happiness of children that makes the heart too big for the body".

Background of the Study

An infant is derived from the Latin word infans, meaning "unable to speak" or "speechless". It refers to the very young offspring of a human or animal. When applied to humans, the term is usually considered synonymous with baby or brain (in Scottish English), but the latter is commonly applied to the young of any animal. The term infant is typically applied to young children between the ages of 1 month and 12 months.

Immunization is the most aversive medical procedures for healthy infants and children and is the most common source of childhood iatrogenic pain. The unpleasant sensory and emotional responses that result from the pain of immunization may induce the fear of needle sticks for these children. Painful procedures are likely to be confounded with anticipatory and concurrent anxiety, usually considered together as procedure related distress.

Pain is highly unpleasant and very personal sensation that cannot be shared with others. International Association for the study of pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential damage or described in terms of such damage. Infants, including new born babies, experience pain similarly and probably more intensely than older children and adults.

They are also at risk of adverse long term effects on behaviour and development, through inadequate attention towards pain relief in early life. Pain can be assessed using self-report, behaviour observation, or physiologic measures, depending on the age of the child and his or her communication capabilities.

Barriers to the treatment of pain in children especially infants do not feel pain as adults do or if they feel pain there is no outward consequence lack of assessment and reassessment for the presence of pain, misunderstanding of how to conceptualize and quantify a subjective experience, lack of knowledge of pain treatment, the notion that addressing pain in children takes too much time and effort and fear of adverse effect of analgesic medication, including respiratory distress and addiction etc.

Minimizing pain associated with childhood vaccination can help to prevent distress, development of needle fears and subsequent health care avoidance behaviours. Parents are likely to have a substantial impact on child's experience of pain. Preparation of a child for a needle procedure varies according to the age of the child. This involves primarily preparing the parents who have infants. However, for toddler and older children, the procedure must be discussed with the child itself.

According to International Association of Pain (2011) despite ready availability, however only 6% of paediatric hospitals use pain control for shots, and 2.1% of an estimated 18 million injections are performed each year with pain control. Distraction for minor to moderate procedural pain is free or inexpensive, easy to perform and is an effective method of pain control. Numerous modalities exist to decrease procedural pain, from topical anaesthetics up to complete deep sedation.

A combination of pharmacological and non-pharmacological interventions can ensure the highest standard of care in the management of pain in children. In infants, ice application prior to intramuscular injection has drastically reduced pain while doing invasive procedures. Cold application slows the nerve impulse in the area, which interrupts the pain spasm reaction between the nerves. The cold makes the vein in the tissue contract, reducing pain. Once the cold is removed, the vein becomes dilate and blood rushes into the area, which in turn has an analgesic effect.

The Gate-Control theory of Melzack and Wall (1965) stated that stimulation of larger diameter fibres (e.g., using appropriate pressure, cold or vibration) can close the neural gate so that the central perception of itch and pain is reduced. It is based on the fact that small diameter nerve fibres carry pain stimuli through a gate mechanism but larger diameter nerve fibres going through the same gate can inhibit the transmission of the smaller nerves carrying the pain signal.

Chemicals released as a response to the pain stimuli also influence whether the gate is opened or closed for the brain to receive the pain signal. This lead to the theory that the pain signals can be interfered with stimulating the periphery of the pain site, the appropriate signal-carrying nerves at the spinal cord or particular corresponding areas in the brain stem or cerebral cortex. It is generally recognized that the pain gate can be shut by stimulating nerves responsible for carrying the touch signal (mechanoreceptors) which enables the relief of pain through massage techniques, rubbing, pressure, cold packs, acupuncture, electrical analgesia and also the application of vibration.

Cold application also known as cryotherapy is one of the most widely used treatment modalities used for acute pain. It is cheap, easy to use and requires little time to prepare. The application of ice to an injury, in the acute phase can substantially decrease the extent of the damage.

Cooling by cold water, spray, air, ice cubes and frozen gel pack are often used to reduce discomfort and mild pain from a variety of sources, such as acute soft-tissue injury, injections, nerve blocks, insertion of intravenous catheters and laser therapy. Only a few local and no systemic side-effects have been reported.

Considering the anxiety due to painful procedures such as injections as well as the unpleasant feelings the parents and the children get, it was hypothesised that the application of local refrigeration would decrease the pain related to injection procedures.

Encountering pain is one of the common paediatric practices. Having worked in the immunization clinic, the investigator came across many infants who were screaming due to pain associated with immunization. This caused psychological impact for parents and difficulties in administering immunization by the health workers. This inspired the investigator to look out for an alternate method which would reduce the pain threshold of infant associated with immunization.

Need For The Study

Pain is an universal, complex and subjective experience. Nurses work in almost all settings and are often associated with people who are suffering from pain.

They spend a lot of time with children who are suffering with pain and suffering than any other health care provider.

The taxonomy committee of International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage.” Each individual learns the application of the word pain through experiences related to injury in early life. Painful medical procedures for children begin with like injections at birth and continue throughout childhood. Children receive immunization injections multiple times throughout childhood and adolescence.

The Centre for Disease Control and Prevention schedule (2012) recommends immunizations against 14 diseases, which translate in to 14 to 20 separate injections before the age of 2 years, depending on the number of combination vaccines available. Therefore, immunizations are the most frequently occurring painful procedures performed in paediatric settings.

National Institute of Health (2011) reports that 77.2% of rural and 80 % of urban children are immunized with vaccines annually. However the children vaccinated will experience severe to moderate pain. Hence there are many non-pharmacological measures to reduce the level of pain, one of which is cold application at the injection site prior to injection.

WHO (2010) reports that injections are among the most frequently used medical procedures with an estimated 12 billion administered throughout the world,

of these 5% or less are for immunization. A conservative estimate of the average number of injection ranged from 0.9 to 8.5 per person every year.

Institute of medicine of the National Academics America (2010) estimated that up to 25% of adults have a fear of needles, with most fears developing in childhood. About 10% of the population avoids vaccination and other needle procedures because of needle fears.

National Centre for Health Statistics (2010) survey at national level showed that 61% of the children aged 12 – 23 months have received full immunization. The coverage of immunization was higher in urban area (67.4%) compared to that in the rural area (58.5%).

Anna Taddi., Moshe Ipp., (2012) conducted a cross-sectional survey regarding the prevalence of immunization non-compliance due to needle fears in 1024 children and 949 parents in Canada by using interviewer administered survey. Convenient sampling technique was used. The study revealed that altogether 24% of parent and 63% of children reported a fear of needle. Intervention aimed at improving education about and access to analgesic interventions associated with immunization injections performed in childhood are recommended in order to prevent the development of needle fear and vaccine non-compliance.

Maryam Modarres., Zam Jazayere., (2012) conducted an experimental study regarding experience of pain in full term neonates associated with injection of Hepatitis B vaccine among 130 neonates in Mirza Kochak Khan Hospital was

selected by using purposive sampling technique. The study concluded that 90% of the neonates have experienced pain.

Larson.M, Baslin.R., Morance.J.J., Harry.B., (2012) conducted an experimental study on reducing pain of childhood vaccination among 78 children by using purposive sampling technique in Los Angels. The study concluded that the coldness may in turn reduce the sensation of pain associated with the vaccine injections.

Neil Schehter M.D., Bruce A., Bernstein., (2011) conducted a descriptive study on to examine the impact of a teaching module on immunization pain reduction practices in paediatric offices among 1 and 6 months of infant's parents after the intervention by using interviews and questionnaire. The finding suggested that parents were likely to use strategies like cold application, providing breast feeding, and administration of sucrose to reduce pain associated with injection.

Shanthi Kumari (2011) conducted an experimental study to assess the effectiveness of ice application on pain reduction prior to intramuscular injection among infants. The sample size was 50 by using purposive convenient sampling technique in Karnataka. The study concluded that ice application was effective in minimizing the pain.

To the child of any age, a visit to the hospital can be at best a frightening event and at worst a traumatizing experience. The children imagine hospital as a place where they get injections. Injections of any kind can hurt when they happen to see a

nurse or a doctor with an injection syringe. The emotional disturbance and fear knows no boundary in children who feel threatened by painful procedures.

Assessing and managing a child with pain is a day to day problem for nurses. Nurses implement the orders and work closely with patients to facilitate healing processes. Application of cold to the injection site is a simple intervention which relieves procedural pain in children and promotes comfort for them. The researcher while working in the pediatric department has assessed that the pain is one of the common problem of the paediatric invasive procedures like intra muscular immunization. These are inevitable in the life of the child but which can be managed by methods like cold application and diversion therapies. So the researcher was interested to select this problem for the dissertation.

Statement Of The Problem

A Study To Evaluate The Effectiveness Of Cold Application On Level Of Pain Associated With Intramuscular Immunization Among Infants In Selected Hospital At Ernakulum.

Objectives

The objectives of the study were

- To assess the post-test level of pain associated with intra muscular immunization among infants in experimental and control group.
- To evaluate the effectiveness of cold application on level of pain associated with intra muscular immunization among infants in experimental group and control group.

- To determine the association between the levels of pain associated with intra muscular immunization among infants with their selected demographic variables in experimental and control group.

Hypotheses

H_1: There is a significant difference between the mean score on level of pain associated with intra muscular immunization among experimental and control group.

H_2: There is a significant association between the levels of pain associated with intra muscular immunization among infants with their selected demographic variables in experimental and control group.

Operational Definition

Evaluate

Evaluate means form an idea of the amount or value of.

In this study, it refers to the determination of level of pain associated with the administration of intramuscular immunization.

Effectiveness

Effectiveness means the desired result produced by an action.

In this study, it refers to the cold application that helps in reducing pain and is evidenced by significant difference in the pain score of infants in the experimental and control group.

Cold Application

Cold application means applying the frozen water.

In this study, it refers to application of small pack filled with crushed ice which is wrapped in a damp towel at the injection site for 30 seconds just prior to intra muscular injection.

Injection Site

Injection site means place which is suitable for introduce a drug into the body with a syringe.

In this study, it refers to the vastus lateralis site. To locate injection site, make an imaginary box on the upper leg. Find the groin one hand's width below the groin becomes the upper border of the box. Find the top of knee. One hand's width above the top of the knee becomes the lower border of the box.

Pain

Pain is a strongly unpleasant sensation caused by illness or injury.

In this study, it refers to the level of discomfort among infants associated with intra muscular immunization a measured by Standardised Neonatal Infant Pain Scale.

Immunization

Immunization means making a person resistant to infection.

In this study, it refers to the pentavalent vaccine given as intra muscular injection against Haemophilus Influenza, Pertussis, Tetanus, Hepatitis B and Diphtheria.

Infant

An infant means a baby or very young child.

In this study, it refers to babies between the age group of 45 days – 12 months.

Assumptions

- Intramuscular injection is a painful procedure.
- Infants experience pain more intensely than older children.
- Cold application reduces discomfort and pain.
- Cold application has no side effects.
- Cold application does not harmful to the patients

Delimitations

- The study is delimited to infants who are undergoing pentavalent vaccine in selected hospital.
- The data collection is delimited to a period of 6 weeks.

Projected Outcomes

- The study will help the nurses to assess the level of pain among infants by using Standardized Neonatal Infant Pain Scale.
- The findings of the study will help the nurses to practicing cold application to reduce pain associated with intramuscular injection.
- The study will help the nurses to identify the effectiveness of cold application on pain associated with intramuscular injection.

- The findings of the study will help the nurse to motivate the co-workers and student to practice cold application to reduce pain associated with intramuscular injection.

CHAPTER II

REVIEW OF LITERATURE

Review of literature is an important step in the development of any research project. A thorough literature review provides a foundation upon which to base new knowledge and generally is conducted well before any data are collected in a quantitative study.

Polit and Hungler (2004) stated that literature review is a critical summary of research on a topic of interest, often prepared to put a research problem in context or as the basis for an implementation projects.

In this study the literatures were reviewed and organized under the following headings;

- Studies related to prevalence of pain during intramuscular immunization among infants.
- Studies related to effectiveness of cold application on pain during intramuscular immunization among infants.

Studies Related To Prevalence Of Pain During Intra Muscular Immunization Among Infants**.**

Annie Morthal., Jonathans AM., (2013) conducted an experimental study on vaccine pain among 113 healthy infants of 4-6 months age receiving their routine DPTap-Hib immunization by using Modified Behavior Pain Scale (MBPS) and Visual

Analogue Scale in primary care center. The study concluded that there was significant pain during immunization and no observed difference in age or birth order.

Champian G D., Diira T., (2012) conducted a descriptive study regarding the factors associated with infant pain response following an immunization injection among 93 infants of 6 – 14 months old by using Neonatal Facial Coding System (NFCS). The study concluded that parental behavior in the treatment room has a key role of influencing how infants respond to painful procedure.

David B Flora., Marriet Oster., (2012) conducted a descriptive study to assess the facial expression and verbalization of pain during immunization among 58 infant of 4 – 6 months by using convenient sampling technique in Canada. The study finding suggested that among them, 53 infants were showing the brief facial expressions.

Cassiay K L., Mc Glath P J., (2011) conducted a descriptive study to assess the expressions of pain on receiving their routine immunizations among 90 infants by using convenient sampling technique. The findings revealed that 60 infants are exploring the pain by other ways like crying and body movements. The most common pain expression is the facial expression following immunization.

Morton Goldbach., Patricia C Parkin., (2011) conducted an experimental study to compare pain response of children who receive intramuscular vaccination in deltoid muscle versus the pain responses of those who receive intramuscular vaccination in vastus lateralis among 185 infant in Turkey. The result indicated that response of infant was similar in each group. Crying duration of the children who received the

vastrus lateralis vaccination was shorter than that of the deltoid group after the procedure.

Khoshtarash M., Ghanbari A., Yeganeh M., (2011) conducted a comparative study on infant pain response to intramuscular injection among 100 infant of 1-8 months of age receiving immunizations by using Modified Behavior Pain Scale score. Standard care group means slow aspiration prior to injection, slow injection and slow withdrawal. Pragmatic group means no aspiration, rapid injection and rapid withdrawal. This study indicates that Modified Behavior Pain Scale scores were higher for the standard group compared to the pragmatic group. The standard group was more likely to cry and to take longer to have the vaccine injected compared to pragmatic group

Studies Related Effectiveness Of Cold Application On Pain During Intramuscular Immunization Among Infants.

Binila T.A., (2013) conducted an experimental study regarding effectiveness of ice application on intramuscular injection pain among 30 infants in Udupi, Karnataka by using Modified Infant Pain Scale .The study concluded that there was intense pain during intramuscular injection and significant reduction in pain after cold application.

Bisy jose, Umrani., (2013) conducted an experimental study on the effect of ice application on reducing pain perception of infants during immunization in Manglore. The sample size was 60 by using convenient sampling technique. The study concluded that ice application was effective in minimization pain.

Cahen T., Cohen L.L., M.C Grath., Zempsky W.T., (2013) conducted a study regarding pain reduction during pediatric immunization among 6 to 36 month old children. The sample size was 100 by using purposive sampling technique. The finding showed that the use of ice pack was effective on reducing in pain perception.

Aaut Callahan M., Iman SL., Swanson B.A., Zillingim., (2012) conducted a quasi-experimental study to determine the effect of local refrigeration prior to intramuscular injection on pain related response among 80 infants. Physiological responses that is blood pressure, pulse and respiration and behavioral responses using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) were assessed. The result of this study suggests that use of local refrigeration prior to intramuscular can be considered an easy and effective intervention for reducing injection related pain.

Anthony C., Karl Landorf., Redmnd., (2012) conducted an experimental study regarding the use of cryotheraphy (ice) applied prior to intramuscular immunization among sixty two participants in Australia. The pain outcome was measured on a Visual Analogue Scale. The result showed that icing the intramuscular injection site is effective and inexpensive method to reduce the discomfort of pain related injection.

Derek Stephens., Julia Sorran., Sarah Smaet., (2012) conducted an experimental study to determine the effectiveness of two non-pharmacological measures such as cold therapy and distraction as pain management method for intramuscular immunization among 90 children aged from 6 – 12 months old by purposive sampling in a health center by using interview and questionnaire OUCHER scale was used to measure intensity of pain. The findings suggested that pain intensity was higher in control group than the experimental group.

Rebecca Billai Riddell., Sara Ahola Kohut., (2012) conducted longitudinal study to investigate the development of negative infant facial expression in response to immunization pain over the first year of life among 100 infants during their 2, 4, 6, and 12 month routine immunization. Infant facial expressions were coded using baby FCS (facial coding system). The results demonstrated that infants displayed a variety of generalized pain and distress faces due to intensity of pain following immunization.

Cache Martin G., Oyeleye B.A., (2012) conducted an experimental study regarding the efficacy of pain relief strategies among infants receiving intramuscular immunization for Diphtheria, Pertussis and Tetanus among 60 infants in East Nigeria. The infants in the breast feeding group were breastfed by their mother 60 minutes and other group applied ice pack for 60 minutes before the immunization, control group received no intervention. The research findings showed that most breastfed infants (55%) and most of those who had applied ice pack (60%) responded moderately to pain.

Christeena., (2012) conducted an experimental study on effectiveness of ice application at selected point (L_1-L_4) prior to intra muscular injection on reducing pain among 60 children between 15-18 months attending the immunization clinic. Ice application was given for children under experimental group for 30 seconds prior to intramuscular injection. Assessment of pain was done immediately for one minute by using Wong and Backer faces pain scale. The study finding revealed that majority (80%) of the children in experimental group had mild pain level after ice application.

Neethu A.M., (2012) conducted a quasi-experimental study on effectiveness of ice application on injection site on reducing pain among 60 infants of 1-12 months in primary health center at Bangalore by using FLACC scale. The study concluded that application of ice before intramuscular injection reduces the pain.

Carbajal R, Gray L, Miller LW Veerapen S A.,(2012) conducted randomized controlled trial to determine the effects of ice application on pain relief among 40 children of age group 1-4 years undergoing vaccine injections in a local hospital, Toronto. Ice or cold packs was applied to the intervention group members on the injection site immediately before the procedure (within 1 minute of injection) and routine care for control group. Pain was measured with a numeric rating scale and measuring vital signs. Children who were provided with ice application had a lower degree of discomfort than children who were not provided with this intervention.

Aliwalas LL., Hassett AL., Gevirtz RN Shah PS., (2012) conducted a randomized controlled clinical trial to assess the effectiveness, feasibility, and parental acceptance of a simple combination pain reduction intervention for infants receiving multiple immunization injections among 116 infants in an academic hospital-based primary care center, USA. Infants receiving immunizations were randomly assigned to the cold application or other group for tactile stimulation and were held by their parents during immunization. The control group did not receive these interventions (standard practice).The result suggested that parents of the intervention group reported a stronger preference for future use of the combination pain reduction intervention procedure.

Adeoye OT., Osinaike BB., Oyedeji AO., (2011) conducted a true experimental study to assess the effectiveness of ice application prior to intramuscular injection in reduction of pain among 50 children in Mangalore. Children were selected randomly and ice applications were given only for experimental group for 30 seconds. The study findings revealed that 85% of the children in the experimental group had mild pain perception level after ice-application and children in the control group had moderate to severe pain.

Akhavan Karbasi S., Eslami Z., Hashemi A., Mirnaseri F., (2011) conducted an experimental study on to assess the non-pharmacological techniques among 90 infants in London by using convenient sampling technique. The techniques which are used for the study are distraction, cold application, massage that help to reduce pain perception during intramuscular injection. The findings suggest that the non-pharmacological techniques which are used to control pain decrease anxiety and enhance the effects of analgesics.

Codipietro L., Ceccarelli M., Ponzone A., (2011) conducted a quasi-experimental study to assess effect of cold application on pain relief during immunizations among 120 infants in Jordan by using Facial Pain Rating Scale and Neonatal/Infant Pain Scale (NIPS) before and after the procedure. Infant's heart rate and duration of crying for both groups were calculated. The findings revealed that the crying time was shorter in intervention (cold application) group than in the control group with a statically significant difference in the duration of crying during and after immunization.

Hassett AL., Gevirtz R., (2011) conducted a randomized controlled trial to compare the acute pain response of infant during immunization using a cold application versus oral sucrose solution among 110 infants aged 4-6 months. The intervention groups were given cold application and oral sucrose solution. Immediate infant pain was measured by the Modified Behavior Pain Scale. The findings suggested that Mean Modified Behavior Pain Scale score were higher for standard group (5-6) compared to pragmatic group (3-3).

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Mitra Savabi Esfahani., Sanaz Sheykhi., Zahra Abdeyazdan., (2011) conducted a quasi-experimental study to determine the effectiveness of cryotherapy in reducing pain during intramuscular injection among 70 children in Canada by using purposive sampling technique. The method used was applying the cold to the injection site before and after the injection. The result revealed that there is a significant reduction of pain during vaccine administration

CONCEPTUAL FRAMEWORK

WIEDENBACH'S HELPING ART CLINICAL NURSING THEORY (1964)

A conceptual framework is the precursor of the theory, conceptual framework play several interrelated roles in progress of sciences. Their overall purpose is to make scientific studies meaningful and generalizable.

Polit and Hungler (1995) states that a conceptual framework is the interrelated concepts or abstractions that are assembled together in the relevance to the common theme. It is a device that helps to stimulate research and extension of knowledge by providing both directions and impetus.

The present study aims to evaluate the effectiveness of cold application on pain associated with intramuscular immunization among infants. The conceptual framework of the study was based on Wiedenbach's Helping Art Clinical Nursing Theory (1964).

Wiedenbach (1964) proposed the theory as a prescriptive theory of nursing. Prescriptive theory directs action towards an explicit goal.

The theory includes 3 factors: central purpose, prescription and realities. A nurse develops a prescription based on a central purpose and implements it according to the realities of the situation.

Central Purpose

Central purpose in the theory refers to what the nurse want to accomplish. It is the overall goal towards which a nurse strives; it transcends the immediate intent of the assignment or task by specifically directing activities towards the patient's benefits.

In this study, the central purpose refers to reduce the level of pain associated with intramuscular immunization among infants.

Prescription

Prescription refers to the plan of care for a patient. It specifies the nature of the action that will fulfill the nurse's central purpose and rationale for the action.

In this study, cold application is given just prior to inserting the needle as an intervention to reduce the level of pain associated with intramuscular immunization among infants.

Realities

Realities refer to the physiological, physical, emotional and spiritual factors that come into play in a situation involving nursing actions.

In this study, age, sex, weight, history of allergic reaction due to intramuscular immunization of the infant was physiological factors. Positions of child during injection, previous experience of cold application, order of vaccine and previous exposure to intramuscular immunization were physical factors.

According to Wiedenbach nursing practice consists:

- Identifying the need for help.
- Ministering the needed help.
- Validating whether the need was met.
- Co-ordination.

Identifying the Need for Help

It involves viewing the patient as an individual with unique experience and understanding the patient's perception of condition. Determining a patient's need for help based on the existence of a need whether the patient realize the need which prevents the patient from meeting the need whether the patient could meet the need alone.

In this study, it involves identification of the need for reduction in level of pain associated with intramuscular immunization among infants by using Standardized Neonatal Infant Pain Scale.

Ministering the Needed Help

It refers to the provision of needed help. It requires an identified need and a patient who wants help.

In this study, Cold application is giving just prior to inserting the needle as an intervention to reduce the level of pain associated with intramuscular immunization among infants.

Validating whether the Need was met

It refers to a collection of evidence that shows whether a patient's needs have been met and his functional ability has been restored due to direct result of the nurse's actions. It based on patient oriented evidence.

In this study, it evaluates the effectiveness of cold application by using Standardized Neonatal Infant Pain Scale. A positive outcome represents satisfaction of infants with decreased pain perception by Cold application and the intervention is reinforced and the negative outcome represents dissatisfaction of infants with increased pain perception.

Co-ordination

Co-ordination is by reporting, consulting and conferring to the client.

In this study it refers to reporting, consulting and conferring with the physician, nurses, patient and family members regarding the effectiveness of Cold application.

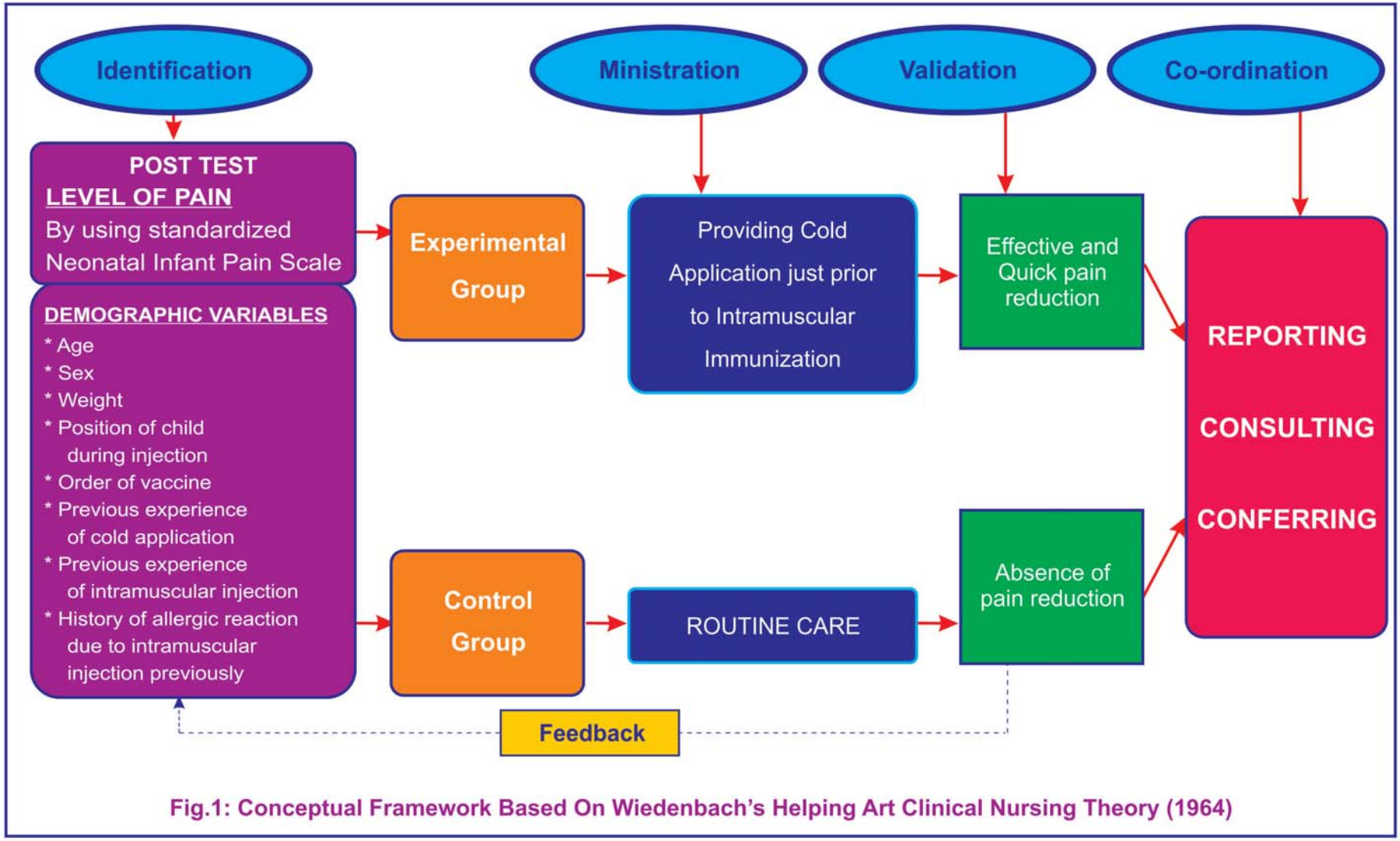

Fig.1: Conceptual Framework Based On Wiedenbach's Helping Art Clinical Nursing Theory (1964)

CHAPTER III

RESEARCH METHODOLOGY

According to Polit and Hungler (2011) research methodology refers to investigating the ways of obtaining, organizing and analyzing data. The present chapter consists of research approach, research design, setting of the study, study population and criteria for a sample selection, sampling technique, development and description of the tool, pilot study, scoring procedure for data collection and procedure for data analysis.

Research Approach

Polit and Hungler, (2004) defined the research approach as "a general set of orderly discipline procedure used to acquire information".

The research approach used for this study was quantitative approach to evaluate the effectiveness of cold application on level of pain associated with intramuscular immunization among infants.

Research Design

According to Nancy Burns (2011) "the research design is the blue print for conducting the study that control over factors that could interfere with the validity of the findings"

A Quasi- experimental post-test only with control group design was chosen for the study without randomization. Standardized Neonatal Infant Pain Scale was used to assess the level of pain among infants receiving intra muscular immunization.

The diagrammatic representation of the research design is given as follows:

Group	Intervention	Posttest
Experimental Group(E)	X	O_1
Control group(C)	_	O_2

Key

O_1,O_2 : Post-test assessment of pain associated with intramuscular immunization among infants in experimental and control group respectively

X : Application of small pack filled with crushed ice which is wrapped in a damp towel at the injection site for 30 seconds just prior to intra muscular immunization.

O_2–O_1 : Effectiveness of cold application on level of pain associated with intramuscular immunization.

Variables

A variable is an attribute of a person or object that varies, that is, takes on different values. Variables are measurable characteristics of a concept and consist of logical group of attributes.

Dependent Variable

Dependent variable is that which is hypothesized to depend on (or) been caused by another variable. In this study the dependent variable is the level of pain associated with intramuscular immunization among infants.

Independent Variable

Independent variable is manipulated and it intends to cause a change in the dependent variables. In this study the independent variable is cold application.

Setting of the Study

Polit and Hungler (2004) stated that "the physical location and conditions in which data collection has taken place in a study is the setting of the study".

The study was conducted in Taluk Hospital, Palluruthy at Ernakulum. It is a100 bedded hospital with different departments like medical surgical, pediatrics, gynecology, orthopedics, neurology, gastroenterology and urology. The hospital has separate operation theater and a well-equipped laboratory. In the outpatient and inpatient department, 800 and 300 cases respectively registered monthly. The samples were selected from the outpatient department of the hospital.

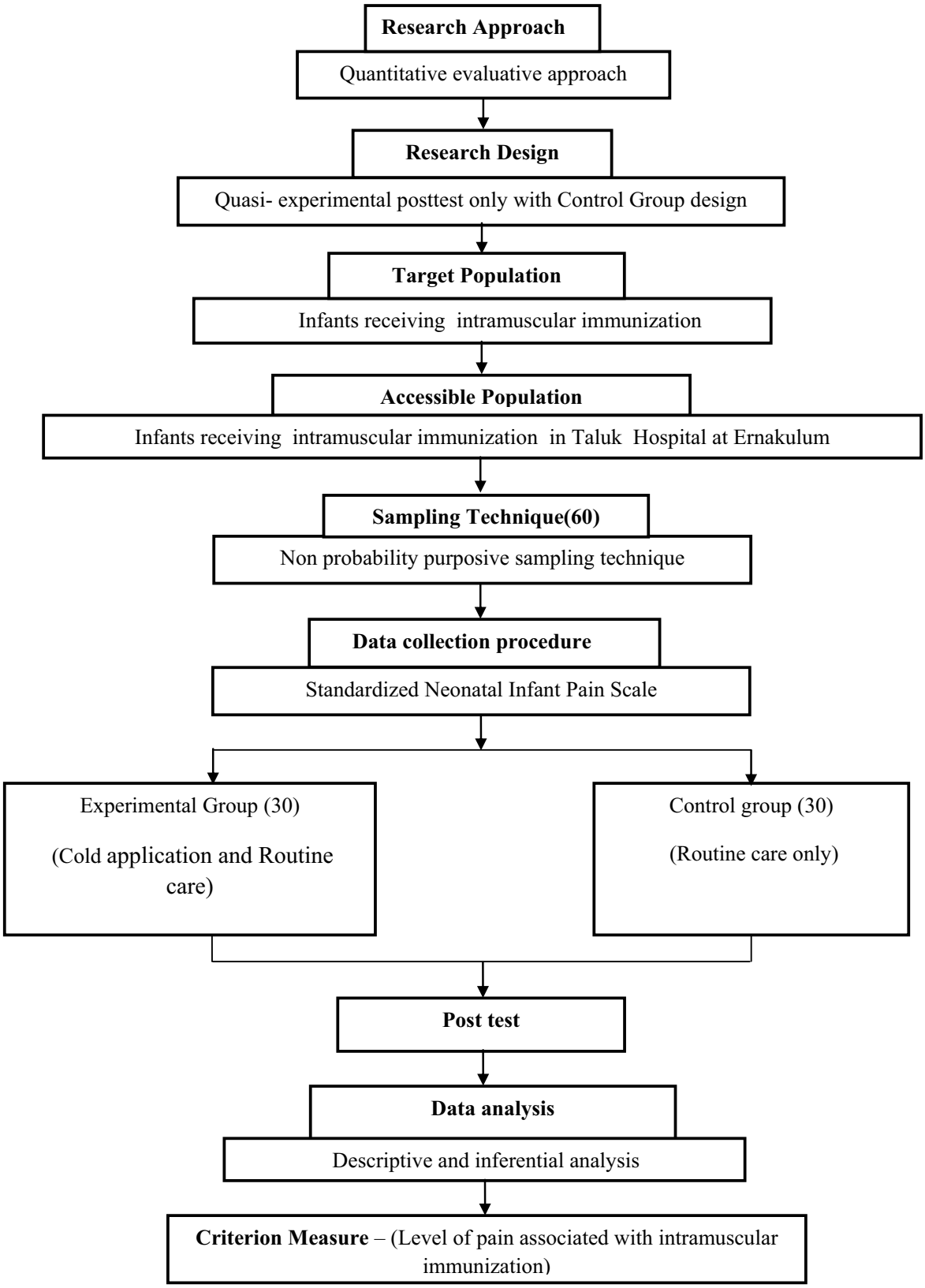

Figure 2: The Schematic Representation Of Research Methodology

Population

According to Polit and Hungler, (2005) “A population is the entire aggregation of cases in which a researcher is interested”.

The target population is the aggregation of cases about which the researcher would like to make generalization. An accessible population is the section of the target population to which the researcher has reasonable access. In this study the target population was infants receiving intramuscular immunization. The accessible population was infants receiving intramuscular immunization in Taluk Hospital at Ernakulum.

Sample

According to Basavanthappa B.T, (2005) “sampling is a process of selecting representative units of a population for study in a research. It is the process of selecting a subset of a population in order to obtain information regarding a phenomenon in a way that represents the entire population”.

The sample size for the study was 60. The subjects were selected in Taluk hospital at Ernakulum.

Sampling Technique

According to Burns and Groove, (2005) “sampling technique is the process of selecting a portion of the population to represent the entire population”.

The samples of the study were selected by adopting non probability purposive sampling technique. The total sample size was 60 and which means, selection of infants who are receiving intramuscular immunization. 30 samples were selected separately for experimental and control group based on inclusion criteria and exclusion criteria.

Criteria for Sample Selection

Inclusion criteria

Infants,

- Healthy infants receiving their routine intramuscular immunization.
- Whose parents, caregivers are willing to participate.
- Those infants receiving pentavalant immunization.

Exclusion criteria

- Impaired neurological development.
- History of seizure
- Use of sedatives or narcotics in the preceding 24 hours.
- Fever or illness that would prevent administration of vaccine.
- Parent who are not willing to participate.
- Infants receiving any other injections other than immunization.
- Severe allergic reaction or encephalopathy to a previous pentavalent immunization

Development of the Tool

Treece and Treece (1986) emphasized that the instrument selected in research should as far as possible be the vehicle that could best obtain data for drawing conclusion pertinent to the study.

The research tool was developed in English after an extensive review of literature and expert opinion. The standardized Neonatal Infant Pain scale was used as the instrument to measure the pain.

Description of tool

The tool consists of two parts

Part I : It includes age, sex, weight, position of child during immunization, order of vaccine, previous experience of cold application, and previous experience of intramuscular immunization, history of allergic reaction due to intramuscular immunization.

Part II : Standardised Neonatal Infant Pain Scale was used to assess the level of immunization pain in infants.The Neonatal Infant Pain Scale (NIPS) is a behavioral assessment tool for measurement of pain in preterm and full-term neonates, birth to 1 year. This can be used to monitor a Neonate before during and after a painful procedure such as venipuncture. It was developed at the Children's Hospital of Eastern Ontario and adapted from CHEOPS scale.This tool includes six categories of pain behaviours including facial expression, cry, breathing pattern, arms, legs, state of arousal.

NEONATAL INFANT PAIN SCALE		
PARAMETER	FINDING	POINTS
Facial Expression	Relaxed	0
	Grimace	1
Cry	No cry	0
	Whimper	1
	Vigorous crying	2
Breathing Patterns	Relaxed	0
	Change in breathing	1
Arms	Restrained	0
	Relaxed	0
	Flexed	1
	Extended	1
Legs	Retrained	0
	Relaxed	0
	Flexed	1
	Extended	1
State of Arousal	Sleeping	0
	Awake	0
	Fussy	1

Each behavioural indicator is scored with 0 or 1 except “cry” which has three possible descriptors therefore, being scored with 0,1 or 2. Infants should be observed for 1 minute in order to fully assess each indicator. Total pain scores range from 0 – 7.

Scoring Procedure

Regarding pain score, the maximum score is 7 and minimum score is 0. The score was divided into the following categories.

0 - 1 : No pain

2 -3 : Mild pain

4- 5 : Moderate pain

6 - 7 : Severe

Intervention

After securing written permission from the respective authority and based on the inclusion and exclusion criteria the sample was selected. Informed consent was taken from the mother or caregiver. After explaining the study, ice pack was applied for 30 seconds prior to intramuscular immunization. At the end of this period intramuscular immunization was given during which pain assessment was done among infants in experimental group for one minute using Neonatal Infant Pain Scale. The pain assessment among control group was done without the intervention.

Validity

According to Burns and Groove, (2005) " the validity of an instrument is the determination of the extent to which the instrument reflect the abstract construct that is being examined".

Five experts in nursing and two experts in medicine evaluated the content validity of the instrument. Nursing experts were child health nursing and medical experts were of pediatric department.

Reliability

According to De Vos., (1998) reliability refers to "the accuracy and consistency of a measuring instrument". An instrument can be considered reliable if it yields similar results on separate occasions.

In this study, Standardized Neonatal Infant Pain Scale was used to assess level of pain associated with intramuscular immunization, is a reliable tool.

Pilot Study

Polit and Beck,(2004) denote that "pilot study is a small-scale version or trial run done in preparation of major study".

The researcher conducted pilot study among 10 infants in Taluk Hospital, Tripunithura at Ernakulum after obtaining the written permission. The purpose was to find out the feasibility of the study. It was found to be feasible.

Data Collection Procedure

The data collection procedure was done for a stipulated period of 6 weeks in Taluk Hospital at Ernakulum. Permission to conduct the study was obtained from the Superintendent of the hospital. The samples were informed by the researcher about the nature and the purpose of the study.Informed consent was taken from the mother or caregiver. After explaining the study, ice pack was applied for 30 seconds prior to intramuscular immunization. At the end of this period intramuscular immunization was given during which pain assessment will be done among infants in experimental group for one minute using Standardized Neonatal Infant Pain Scale. The pain assessment among control group was done without the intervention.

Plan for Data Analysis

The data was analyzed by using descriptive and inferential statistics. The demographic variables were analyzed by using descriptive measures (frequency and percentage).The pain was analyzed by using descriptive statistics (mean , standard deviation). The effect of cold application on pain associated with intramuscular immunization was analyzed by using independent‘t’ test. Association between pain associated with intramuscular immunization and the selected demographic variables were analyzed by using chi square test.

Protection on Human Rights

The study was conducted after the approval of ethical committee in taluk hospital and research committee of the college of nursing. The nature and purpose of the study was explained to the care personnel involved. The informed written consent was obtained from the study participant. The anonymity of the sample was maintained throughout the study.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of the collected data from 60 infants to assess the effectiveness of cold application on pain associated with intramuscular immunization. The purpose of analysis was to reduce the data to an intangible and interpretable form, so that the relation of the research problem can be studied and tested.

Polit and Beck (2003) has noted data analysis as "the systematic organization, synthesized research data and testing of research hypothesis using those data"

The analysis and interpretation of data of the study are based on data collected through Standardized Neonatal Infant Scale among 60 infants. The result were computed by using descriptive (Mean, Frequency, Percentage Distribution, and Standard Deviation) and inferential statistics (paired 't' test and chi square).

The study findings are presented in sections as follows:

Section I : Data on demographic variables of immunized infants.

Section II : Data on level of pain associated with intramuscular immunization among Infants.

Section III : Data on effectiveness of cold application on levels of pain associated with intramuscular immunization among infants.

Section IV : Data on association between the levels of pain associated with intramuscular Immunization among infants with their selected demographic variables in experimental group and control group.

SECTION I : DATA ON DEMOGRAPHIC VARIABLES OF INFANTS.

Table: 1.1

Frequency And Percentage Distribution Of Demographic Variables Among Infants In Experimental Group.

N=30

S.No	Demographic Variables	Frequency (f)	Percentage (%)
1	Age (in months)		
	a. 1.5-2 months	12	40
	b. 2.5-3 months	11	37
	c. 3.5-4 months	7	23
2	Gender		
	a. Male	10	33
	b. Female	20	67
3	Weight		
	a. 2-4 kg	5	17
	b. 5-7 kg	20	67
	c. 8-10 kg	5	16
4	Position of child during immunization		
	a. Sitting (holding with parents)	27	90
	b. Lying	3	10
5	Order of vaccine		
	a. Penta1	13	43
	b. Penta2	11	37
	c. Penta3	6	20

(Contd.,)

S. No.	Demographic variables	Frequency (f)	Percentage (%)
6	Previous experience of cold application		
	a. Yes	0	0
	b. No	30	100
7	Previous experience of intramuscular immunization		
	a. Yes	17	57
	b. No	13	43
8	History of any allergic reaction due to intra muscular immunization previously		
	a . Yes	0	0
	b . No	30	100

Table reveals that regarding age, majority of the immunized infants 12(40%) belong to the age group of 1.5 – 2 months, 11(37%) belong to 2.5 – 3 months, 7(23%) belong to the age 3.5 – 4 months.

Regarding gender immunized infants were 20(67%) and 10(33%) were males.

Regarding weight 20(67%) of immunized infants belong to 5 – 7kg, 5(17%) belong to 2 – 4kg and 5(16) belong to 8 – 10kg

Regarding position of child during immunization 27(90%) of the infants were maintained sitting position and 3(10%) of the infants were maintained lying position.

Regarding order of vaccine 13(43%) had received penta1 vaccine, 13(37%) had received penta2 vaccine and 6(20%) had received penta3 vaccine.

Regarding previous experience of ice application 30(100%) had no previous experience of ice application.

Regarding previous experience of intramuscular immunization 17(57%) had previous experience and 13(43%) had no previous experience of ice application.

Regarding history of allergy 30(100%) had no previous history of allergic reaction.

It reveals that immunized infants having pain associated with intramuscular immunization majority of them belong to age group 1.5 – 2 months, were females, had 5–7 kg, maintained sitting position, received penta3 vaccine, had no previous history of cold application, had previous experience of intramuscular immunization, had no history of allergic reaction due to intramuscular immunization previously.

.

Table: 1.2

Frequency And Percentage Distribution Of Demographic Variables Among Infants In Control Group.

N=30

S.No	Demographic Variables	Frequency (f)	Percentage (%)
1	Age (in months)		
	a) 1.5-2 months	9	30
	b) 2.5-3 months	7	23
	c) 3.5-4 months	14	47
2	Gender		
	a) Male	16	53
	b) Female	14	67
3	Weight		
	a) 2-4 kg	6	20
	b) 5-7 kg	15	50
	c) 8-10 kg	9	30
4	Position of child during immunization		
	a) Sitting (holding with parents)	28	93
	b) Lying	2	67
5	Order of vaccine		
	a) Penta1	9	30
	b) Penta2	8	27
	c) Penta3	13	43

(Contd.,)

S. No.	Demographic variables	Frequency (f)	Percentage (%)
6	Previous experience of cold application		
	a) Yes	0	0
	b) No	30	100
7	Previous experience of intramuscular immunization		
	a) Yes	21	70
	b) No	9	30
8	History of any allergic reaction due to intra muscular immunization previously		
	a) Yes	0	0
	b) No	30	100

Table reveals that regarding age, majority of the immunized infants 14(47%) belong to the age group of 3.5 – 4 months, 9(30%) belongs 2.5 – 3 months, 7(23%) belong to the age 1.5 – 2 months.

Regarding gender immunized infants 16(67%) were males and 14(47%) were females.

Regarding weight 15(50%) of immunized infants belongs 5 – 7kg, 9(30%) belong to 8 – 10kg and 6(20%) belong to 2 – 4kg.

Regarding position of child during immunization 28(93%) of the infants were maintained sitting position and 2(7%) of the infants were maintained lying position.

Regarding order of vaccine 13(43%) had received penta3 vaccine, 9(30%) had received penta1 vaccine and 8(27%) had received penta2 vaccine.

Regarding previous experience of cold application 30(100%) had no previous experience of cold application.

Regarding previous experience of intramuscular immunization 21(70%) had previous experience and 9(30%) had no previous experience of cold application.

Regarding history of allergy 29(97%) had no previous history of allergic reaction and 1(3%) had history of allergic reaction

It reveals that infants having pain associated with intramuscular immunization majority of them belong to age group 3.5 – 4 months, were males, had 5 – 7 kg, maintained sitting position during immunization, received penta3 vaccine, had no previous history of cold application, had previous experience of intramuscular immunization, had no history of allergic reaction due to intramuscular immunization previously.

SECTION II: DATA ON LEVEL OF PAIN ASSOCIATED WITH INTRAMUSCULAR IMMUNIZATION AMONG INFANTS

Table: 2.1

Frequency And Percentage Distribution Of Posttest Level of Pain Associated With Intramuscular Immunization Among Infants In Experimental Group

N=30

Sl. No.	Level of Pain	Frequency (f)	Percentage (%)
1	No pain	0	0
2	Mild pain	21	70
3	Moderate pain	9	30
4	Severe pain	0	0

The above table shows that among 30 immunized infants in experimental group, 21 (70%) had mild pain and 9(30%) had moderate pain during Post test.

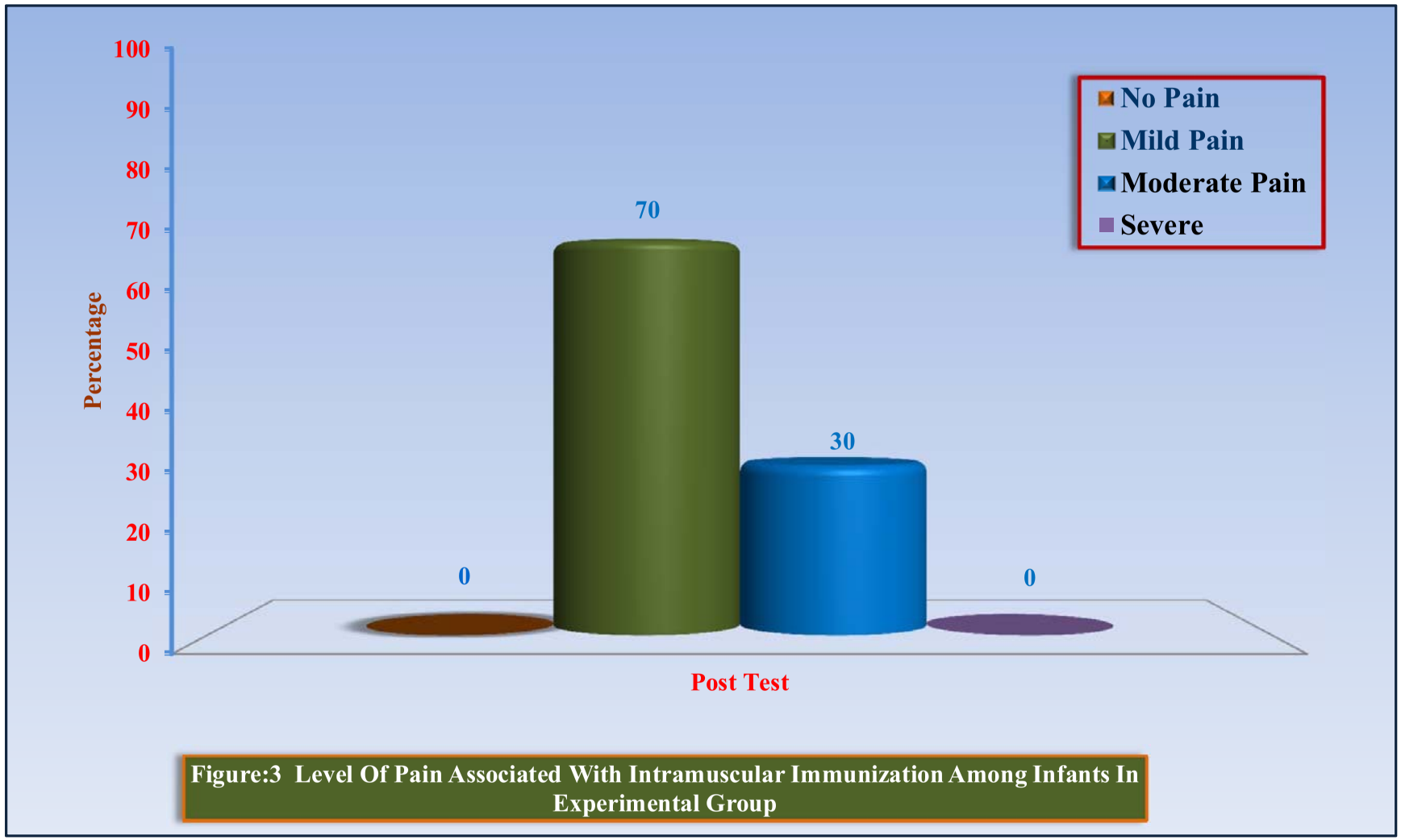

Figure:3 Level Of Pain Associated With Intramuscular Immunization Among Infants In Experimental Group

Table: 2.2

Frequency And Percentage Distribution Of Posttest Level Of Pain Associated With Intramuscular Immunization Among Infants In Control Group.

N=30

Sl. No.	Level of Pain	Frequency (f)	Percentage (%)
1	No pain	0	0
2	Mild pain	0	0
3	Moderate pain	10	33
4	Severe pain	20	67

The above table shows that among 30 immunized infants in control group, 20(66.67%) experienced severe pain and 10(3.33%) experienced moderate pain during post test.

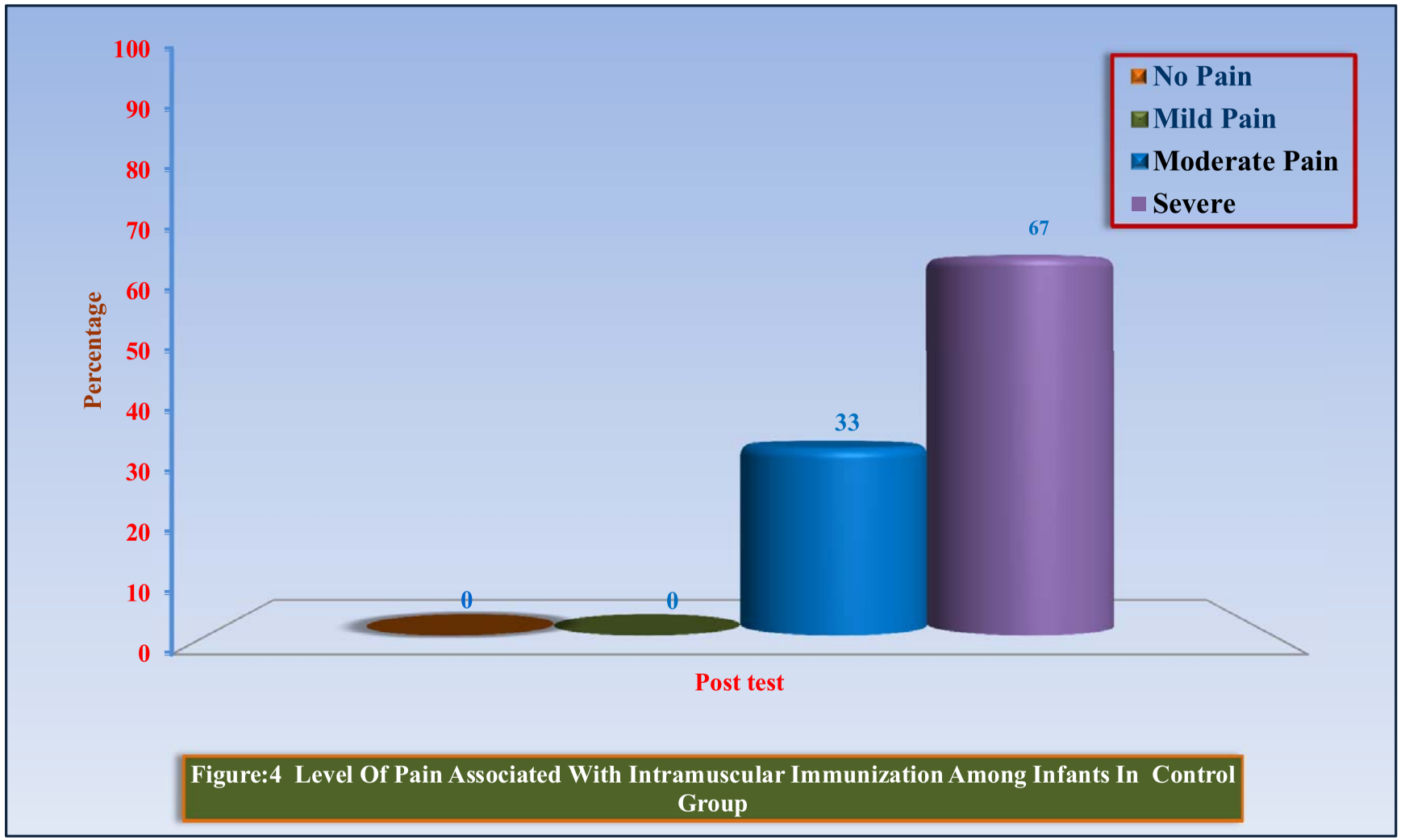

Figure:4 Level Of Pain Associated With Intramuscular Immunization Among Infants In Control Group

SECTION III : DATA ON EFFECTIVENESS OF COLD APPLICATION LEVEL OF PAIN ASSOCIATED WITH INTRA MUSCULAR IMMUNIZATION AMONG INFANTS

Table: 3.1

Mean, Standard Deviation, Mean Difference And 't' Value Of Posttest Level Of Pain Associated With Intramuscular Immunization Among Infants.

N=30

S.NO.	Level of Pain	Mean	Standard Deviation	Mean Difference	't' Value
1. 2.	Experimental group Control group	3.2 5.8	1.1	2.6	9.13*

* - Significant at $p<0.05$ level

Table 3 reveals that among infants, the mean experimental group score was 3.2 and the mean control group score was 5.8 with the standard deviation 1.1. The calculated mean difference was 2.6 and the obtained 't' value 9.13 was significant at $p<0.05$ level. Hence the stated hypothesis (H_1) was accepted. It was inferred that there is a significant difference between mean post- test levels of pain associated with intramuscular immunization among infants in experimental and control group.

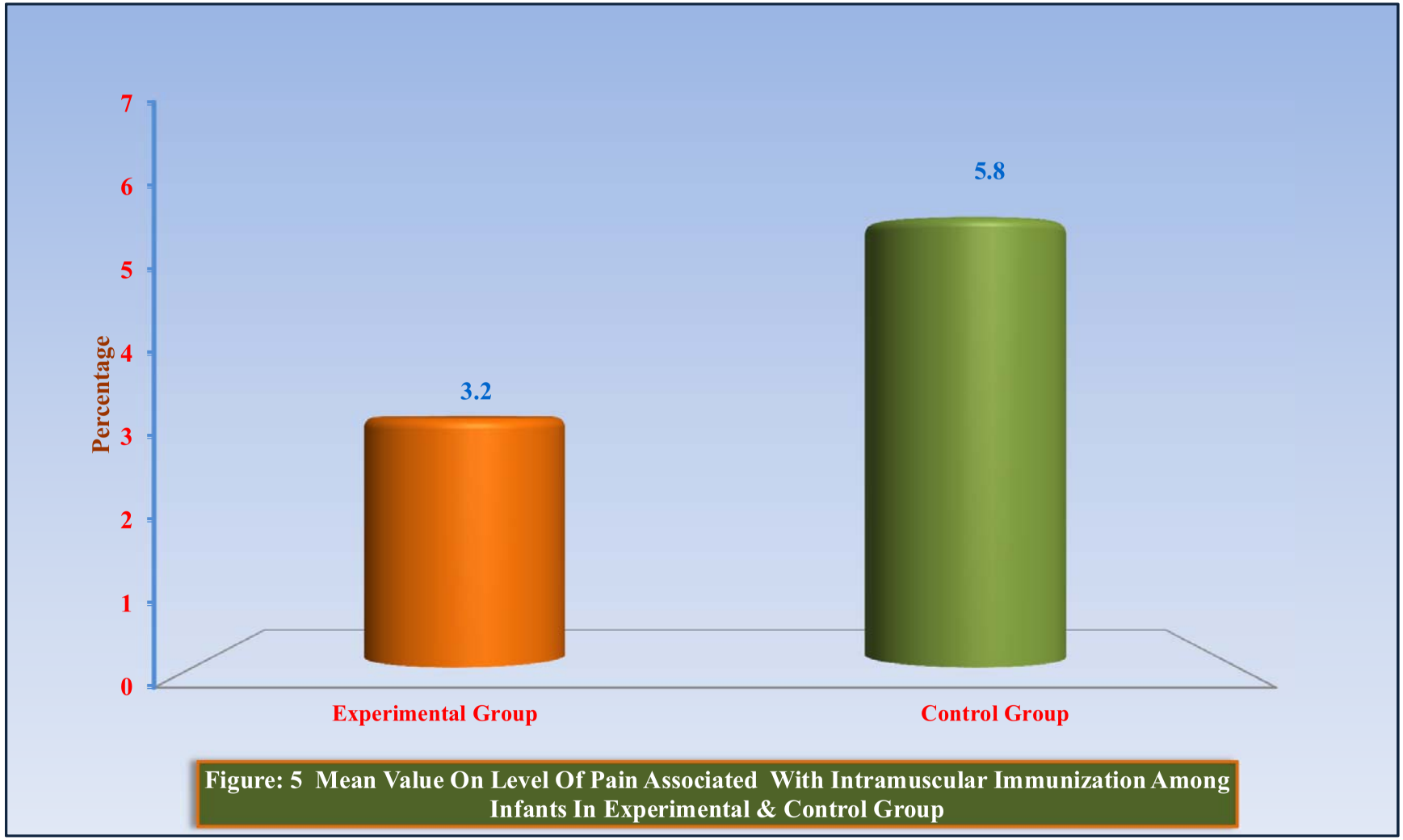

Figure: 5 Mean Value On Level Of Pain Associated With Intramuscular Immunization Among Infants In Experimental & Control Group

SECTION IV: DATA ON ASSOCIATION BETWEEN LEVEL OF PAIN ASSOCIATED WITH INTRAMUSCULAR IMMUNIZATION AMONG INFANTS WITH THEIR SELECTED DEMOGRAPHIC VARIABLES IN EXPERIMENTAL GROUP AND CONTROL GROUP.

Table: 4.1

Frequency, Percentage and χ^2 Distribution On Posttest Level of Pain Associated With Intramuscular Immunization Among Infants With Their Selected Demographic Variables In Experimental Group.

N=30

S. No.	Demographic Variables	Level of Pain				χ^2 Value
		Mild Pain		Moderate Pain		
		f	%	f	%	
1.	Age (in months)					
	a. 1.5-2 months	8	27	4	13	2.86^{NS}
	b. 2.5-3 months	8	27	3	10	df=2
	c. 3.5-4 months	5	16	2	7	
2.	Gender					
	a. Male	5	17	5	17	2.86^{NS}
	b. Female	16	53	4	13	df=1
3.	Weight					
	a. 2 – 4kg	2	7	3	10	6.42
	b. 5 – 7kg	17	56	3	10	df=2
	c. 8 – 10kg	2	7	3	10	
4.	Position of child during immunization					
	a. Sitting (holding with parent)	20	67	7	23	2.13^{NS} df=1
	b. Lying	1	3	2	7	

S. No.	Demographic Variables	Level of Pain				χ^2 Value
		Mild Pain		Moderate Pain		
		f	%	f	%	
5	Order of vaccine					
	a. Penta1	6	20	7	24	6.32*
	b. Penta2	10	33	1	3	df=2
	c. Penta3	5	17	1	3	
6	Previous experience of cold application					
	a. Yes	0	0	0	0	0^{NS}
	b. No	21	70	9	30	df=1
7	Previous experience of intramuscular immunization					
	a. Yes	13	43	4	13	0.78^{NS}
	b. No	8	27	5	17	df=1
8	History of allergic reaction due to intramuscular immunization previously					
	a. Yes	0	0	0	0	0^{NS}
	b. No	21	70	9	30	df=1

^{NS} – Non Significant

* - Significant at $p<0.05$ level

Table 4 envisages the substantive summary of chi square analysis which was used to bring out the relationship between the levels of pain associated with intramuscular immunization among immunized infant with their selected demographic variables.

With regard to age, among 1.5 – 2 months 8(27%) had mild pain 4(13%) had moderate pain. Among 2.5 - 3 months, 8(27%) had mild pain 3(10%) had moderate pain. Among 3.5 - 4 months 5(16%) had mild pain, 2 (7%) had moderate pain. The obtained chi square value of 2.86 was not significant at $p < 0.05$ level. So it is inferred that there is no significant association between the age and level of pain associated with intramuscular immunization among infants.

With regard to gender, among males 5(17%) had mild pain, 5(17%) had moderate pain .Among females 16(53%) had mild pain, 4(13%) had moderate pain. The obtained chi square value of 2.86 is not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between gender and level of pain associated with intramuscular immunization among infants.

With regard to weight, among 2 – 4kg 2(7%) had mild pain, 3(10%) had moderate pain. Among 5 – 7kg 17(57%) had mild pain, 3(10%) had moderate pain. Among 8 – 10kg 2(7%) had mild pain, 3(10) had moderate pain. The obtained chi square value of 6.42 is significant and thus the stated research hypothesis is supported. So it is inferred that there is a significant association between weight and level of pain associated with intramuscular immunization among infants.

With regard to position of child during immunization, among sitting (holding with parent) 20 (67%) had mild pain, 7(23%) had moderate pain. Among lying position 1(3%) had mild pain, 2 (67%) had moderate pain. The obtained chi square value of 2.13 was not significant at $p< 0.05$ level and thus the stated research

hypothesis is not supported. So it is inferred that there is no significant association between educational status and level of pain associated with intramuscular immunization among infants.

With regard to order of vaccine, among penta1 6(20%) had mild pain, 7(23%) had moderate pain. Among penta2 10(33%) had mild pain, 1 (3%) had moderate pain. Among penta3 5(17%) had mild pain and 1 (3%) had moderate pain. The obtained chi square value 6.32 was significant at $p< 0.05$ level and thus the stated research hypothesis is supported. So it is inferred that there is a significant association between order of vaccine and level of pain associated with intramuscular immunization among infants.

With regard to previous experience of cold application, none of them have previous experience in that 21(70%) had mild pain and 9(30%) had moderate pain. The obtained chi square value 0 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between previous experience of cold application and level of pain associated with intramuscular immunization among infants.

With regard to previous experience of intramuscular immunization, those who have previous experience 13(43%) had mild pain, 4(13%) had moderate pain. Those who are not having previous experience of intramuscular immunization 8(27%) had mild pain 5(17%) had moderate pain. The obtained chi square value 2.19 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between previous experience of intramuscular

immunization and level of pain associated with intramuscular immunization among infants.

With regard to history of allergic reaction due to intramuscular immunization previously, among immunized infants none of them having allergic reaction previously. . The obtained chi square value 0 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between history of allergy due to intramuscular immunization and level of pain associated with intramuscular immunization among infants

It was inferred that, there is a significant association between level of pain associated with intramuscular immunization among infants with their selected demographic variable such as weight and order of vaccine. There is no significant association between level of pain associated with intramuscular immunization among infants with their selected demographic variables such as age, sex, position of child during injection, previous experience of cold application, previous experience of intramuscular injection, history of allergic reaction due to intramuscular immunization previously.

Table: 4:2

Frequency, Percentage and χ^2 Distribution Of Posttest Level of Pain Associated With Intramuscular Immunization Among Infants With Their Selected Demographic Variables In Control Group.

N=30

S. No.	Demographic Variables	Level of Pain				χ^2 Value
		Moderate Pain		Severe Pain		
		f	%	f	%	
1.	Age (in months)					
	a. 1.5-2 months	1	3	8	20	4.26^{NS}
	b. 2.5-3 months	2	7	5	17	df=2
	c. 3.5-4 months	7	23	7	23	
2.	Gender					
	a. Male	5	17	11	36	6.63*
	b. Female	5	17	9	30	df=1
3.	Weight					
	a. 2 – 4kg	3	10	3	10	3.12^{NS}
	b. 5 – 7kg	3	10	12	40	df=2
	c. 8 – 10kg	4	13	5	17	
4.	Position of child during immunization					
	a. Sitting (holding with parent)	10	33	18	60	1.08^{NS} df=1
	b. Lying	0	0	2	7	

(Contd.,)

S. No.	Demographic Variables	Level of Pain				χ^2 Value
		Moderate Pain		Severe Pain		
		f	%	f	%	
5	Order of vaccine					
	a) Penta1	1	3	8	27	3.05^{NS}
	b) Penta2	3	10	5	17	df=2
	c) Penta3	6	20	7	23	
6	Previous experience of cold application					
	a) Yes	0	0	0	0	0^{NS}
	b) No	10	33	20	67	df=1
7	Previous experience of intramuscular immunization					
	a) Yes	7	23	14	47	0^{NS}
	b) No	3	10	6	20	df=1
8	History of allergic reaction due to intramuscular immunization previously					
	a. Yes	0	0	0	0	0^{NS}
	b. No	10	33	20	67	df=1

^{NS} – Non Significant

* - Significant at $p<0.05$ level

Table 4 envisages the substantive summary of chi square analysis which was used to bring out the relationship between the levels of pain associated with intramuscular immunization among immunized infant with their selected demographic variables.

With regard to age, among 1.5 – 2 months 1(3%) had moderate pain 8(27%) had severe pain. Among 2.5 - 3 months, 2(7%) had moderate pain 5(17%) had severe pain. Among 3.5 - 4 months 7(23%) had moderate pain, 7 (23%) had severe pain. The obtained chi square value of 4.26 was not significant at $p < 0.05$ level thus stated hypothesis is not supported. So it is inferred that there is no significant association between the age and level of pain associated with intramuscular immunization among infants.

With regard to gender, among males 5(17%) had moderate pain, 11(37%) had severe pain. Among females 5 (17%) had moderate pain, 9(30%) had severe pain. The obtained chi square value of 6.63 was significant and thus the stated research hypothesis is supported. So it is inferred that there is a significant association between gender and level of pain associated with intramuscular immunization among infants.

With regard to weight, among 2 – 4kg 3(10%) had moderate pain, 3(10%) had severe pain. Among 5 – 7kg 3(10%) had moderate pain, 12(40%) had severe pain. Among 8 – 10kg 4(13%) had moderate pain, 5(17%) had severe pain. The obtained chi square value of 3.12 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between weight and level of pain associated with intramuscular immunization among infants.

With regard to position of child during immunization, among sitting (holding with parent) 10 (33%) had moderate pain, 18(60%) had severe pain. Among lying position 2(7%) had severe pain. The obtained chi square value 1.08 was not significant at $p< 0.05$ level and thus the stated research hypothesis is not supported.

So it is inferred that there is no significant association between position of child during immunization and level of pain associated with intramuscular immunization among infants.

With regard to order of vaccine, among penta1 1(3%) had moderate pain, 8(27%) had severe pain. Among penta2 3(10%) had moderate pain, 5(16.67%) had severe pain. Among penta3 6(20%) had moderate pain and 7 (23%) had severe pain. The obtained chi square value 3.05 was not significant at $p< 0.05$ level and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between order of vaccine and level of pain associated with intramuscular immunization among infants.

With regard to previous experience of cold application, none of them had previous experience in that 10(33%) had moderate pain and 20(67%) had moderate pain. The obtained chi square value 0 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between previous experience of cold application and level of pain associated with intramuscular immunization among infants.

With regard to previous experience of intramuscular immunization, those who have previous experience 7(23%) had moderate pain, 14(47%) had severe pain. Those who are not having previous experience of intramuscular immunization 3(10%) had moderate pain 6(20%) had severe pain. The obtained chi square value 0 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between previous experience of intramuscular

immunization and level of pain associated with intramuscular immunization among infants.

With regard to history of allergic reaction due to intramuscular immunization previously, among infants none of them had history of allergic reaction previously , among infants who are not having allergic reaction previously 10 (33%) had moderate pain, 20(67%) had severe pain. The obtained chi square value 0 was not significant and thus the stated research hypothesis is not supported. So it is inferred that there is no significant association between history of allergic reaction due to intramuscular immunization previously and level of pain associated with intramuscular immunization among infants.

It was inferred that, there is a significant association between levels of pain associated with intramuscular immunization among infants with their selected demographic variable such as age. There is no significant association between levels of pain associated with intramuscular immunization among infants with their selected demographic variables such as age, weight, order of vaccine, position of child during injection, previous experience of cold application, previous experience of intramuscular injection, history of allergic reaction due to intramuscular immunization previously.

CHAPTER V

DISCUSSION

The basic aim of this study was to evaluate the effectiveness of cold application on level of pain during intramuscular immunization among infant in selected hospital at Ernakulum.

The study was conducted by using Quasi experimental post- test with control group only design. Samples were selected from Taluk hospital for conducting the study. The sample size was 60.

The structured self-administered questionnaire was used to assess the demographic variables among infants with intramuscular immunization. The Standardized Neonatal Infant Pain Scale was used to assess the level of pain associated with intramuscular immunization. The responses were analyzed by using descriptive statistics (mean, frequency, percentage and standard deviation) and inferential statistics (paired 't' test and chi square test). Discussions on the findings were arranged based on objectives of the study.

The first objective was to assess the post-test level of pain during intramuscular immunization among infants in experimental group and control group. The study revealed that during post- test, in experimental group 70% infants had mild pain and 30% infants had moderate pain and none of them had no pain and severe

pain. In control group (33%) infants had moderate pain and (67%) infants had severe pain.

The study finding were similar to the findings of Finkelstein., and Jacobs., (2012) conducted an Qausi-experimental study regarding experience of pain in infants during injection of DPT and Hepatitis B vaccine among 60 infants in St Philomena's Hospital Bangalore by using Modified Neonatal Pain Scale. The study concluded that of the experimental group experience less pain than control group.

The second objective of the study was to evaluate the effectiveness of cold application at injection site on level of pain during intramuscular immunization among infants in experimental group. In experimental group the mean was 3.2 and standard deviation 1.1. The mean difference was 2.6. The obtained t value 9.13 was significant at $p < 0.05$ level .Thus the stated hypothesis is accepted. The study revealed that cold application is effective on pain associated with intramuscular immunization among infants.

The study findings were similar to the findings of Jisy Jose, Umarani., (2013) conducted an experimental study to assess the effectiveness of cold application on pain reduction prior to intramuscular injection among infants. The mean value of experimental group is 3.4 and the standard deviation is 1.15.The obtained t value is 16.89 was significant at $p < 0.05$ level. The study concluded that cold application was effective in minimizing the pain.

The third objective of the study was to determine the association between the level of pain during intramuscular immunization among infants with their selected

demographic variables in experimental and control group. The study revealed that there is significant association between the levels of pain associated with intramuscular immunization among infants with their selected demographic variables such as sex, weight, order of vaccine. There is no significant association between levels of pain associated with intramuscular immunization among infants with their selected demographic variables such as age, position of child during immunization, previous experience of cold application, previous experience of intramuscular injection, history of allergic reaction due to intramuscular immunization previously.

The study findings were similar to the findings of Blount R.L., Joseph P., (2013) conducted an experimental study regarding vaccine related pain among 80 healthy infants of 2-9 months age receiving their routine immunization by using Modified Behavior Pain Scale (MBPS) and Visual Analogue Scale in Primary Health Centre. The study concluded that there was significant association between level of pain during immunization and demographic variables such as age and type of vaccine. There is no significant association between level of pain and demographic variables such as sex and weight.

CHAPTER VI

SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter presents a brief account of the present study. It deals with the summary, conclusion and recommendations of the study. Conclusions drawn from the findings and the implications of the results for nursing practice, nursing education, nursing research and nursing administration are stated.

Summary

The present study was conducted to Evaluate The Effectiveness Of Cold Application On Level Of Pain Associated With Intramuscular Immunization Among Infants In Selected Hospital At Ernakulum

The objectives of the study were

- To assess the post-test level of pain associated with intramuscular immunization among infants in experimental and control group.
- To evaluate the effectiveness of cold application at injection site on level of pain associated with intramuscular immunization among infants in experimental group and control group.
- To determine the association between the levels of pain associated with intramuscular immunization among infants with their selected demographic variables in experimental and control group.

Quasi experimental post-test with control group only design was used to evaluate the effectiveness of cold application on level of pain associated with

intramuscular immunization among infants. Standardized Neonatal Infant Pain Scale was used to collect data to assess the level of pain associated with intramuscular immunization among infants.

Non probability purposive sampling technique was adopted to select the sample with inclusion criteria. Sample size was 60.

Tool consisted of

Part A : demographic variables of age, sex, weight, position of child associated with immunization, order of vaccine, previous experience of cold application, and previous experience of intramuscular injection, history of allergic reaction due to intramuscular immunization.

Section – B: Standardised Neonatal Infant Pain Scale will be used to assess the level of pain associated with intramuscular immunization among infants.

Posttest assessment of data collection was done by using Standardized Neonatal Infant Pain Scale.

The collected data were analyzed by using both descriptive statistics (mean, frequency, percentage and standard deviation) and inferential statistics (independent 't' test and chi square test) and result were drawn.

Major Study Findings:

Major study findings include

- Regarding demographic variables of 60 infants, in experimental group majority of them belong to age group 1.5 – 2 months, were females, had 5 – 7 kg, maintained sitting position during immunization, received penta3 vaccine,

had no previous history of cold application, had previous experience of intramuscular injection, had no history of allergic reaction due to intramuscular injection previously. In control group majority of them belongs to age group 3.5 – 4 months, were males, had 5 – 7 kg, maintained sitting position during immunization, received penta3 vaccine, had no previous history of cold application, had previous experience of intramuscular injection, had no history of allergic reaction due to intramuscular injection previously.

- Regarding effectiveness of cold application on pain associated with intramuscular injection among infants , the mean experimental group score was 3.2 and the mean control group score was 5.8 with the standard deviation 1.1 .The calculated mean difference was 2.6 and the obtained 't' value 9.13 was significant at $p<0.05$ level. Hence the stated hypothesis (H_1) was accepted. It was inferred that there is a significant difference between mean post- test levels of pain associated with intramuscular immunization among infants.
- Regarding association between the levels of pain associated with intramuscular immunization with their selected demographic variables, there was significant association between sex, weight, and order of vaccine. There is no significant association between demographic variables such as age, position of child associated with immunization, previous experience of cold application, previous experience of intramuscular injection and history of allergic reaction due to intramuscular immunization previously.

Conclusion

The main conclusion drawn from the present study in most of the infants had mild and moderate pain in experimental group and moderate and severe pain in control group. This shows that the cold application was effective on reducing pain associated with intramuscular immunization among infants.

Implications of the Study

According to Tolsma (1995) the section of the research report that focuses on nursing implication usually includes specific suggestions for nursing practice, nursing education, nursing research and nursing administration. Nursing implication for this study is enlisted below:

Nursing Practice

Clinical nurse can

- Learn the techniques of cold application.
- Learn accurate assessment of pain with use of Standardized Neonatal Infant Pain Scale.
- Understand the importance of cold application as an adjuvant to the conventional medicine.
- Use cold application as a complimentary therapy to reduce pain associated with intramuscular immunization.
- Use this as a simple technique for reducing pain associated with intramuscular immunization among infants.

- Motivate the student nurses to use cold application to reduce pain associated with intramuscular immunization among infants.
- Suggest this simple technique for preventing further complication associated with intramuscular immunization.

Nursing Education

Nurse educators can motivate student to:

- Learn the effectiveness of cold application on reducing pain associated with intramuscular immunization as an independent nursing intervention.
- Learn the assessment of level of pain associated with intramuscular immunization through the Standardized Neonatal Infant Pain Scale.
- Learn the technique and mechanism of cold application on reducing pain associated with intramuscular immunization.

Nursing Research

Nurse researcher can:

- Add to the research review about the importance of cold application.
- Conduct further research in different setting using the above findings as a base line data.
- Expanding the scientific body of professional knowledge upon which further researches can be conducted.
- Help in practice aspect to expand the role of nurse.
- Disseminate the finding through the conference, seminars, publications, national and international journal and World Wide Web.

Nursing Administration

Nurse administrator can:

- Organize in service education programmes for the nurses on this technique.
- Develop a written protocol on method of cold application implication.
- Make staff nurses to focus on the important aspect of cold application to reduce pain associated with intramuscular immunization.

Recommendations

- Similar kind of study can be conducted on a large group.
- A comparative study can be done between the effectiveness of various non-pharmacological measures for pain associated with intramuscular immunization. .
- The same study can be conducted in adult and old age people.
- The same study can be conducted in different settings such as nursing homes, old age homes, and community centers.
- A descriptive study can be conducted on knowledge and attitude regarding cold application.
- The same study can be replicated in larger sample size.
- The study can be conducted with true experimental design.

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APPENDIX A

Letter Requesting Experts Opinion For Content Validity Of The Tools Intervention

ANNAI MEENAKSHI COLLEGE OF NURSING

Affiliated with the Tamil Nadu Dr. M.G.R Medical University, Chennai.
Approved by the Indian Nursing Council, New Delhi &
Tamil Nadu Nurses and Midwives Council, Chennai.

Madukkarai Market Road,
P.B. No. 4431
Industrial Estate Post,
COIMBATORE - 641 021.

0422 - 6562705
94421 75641
98435 24219

Phone : 0422 - 2675641, 2672705
Fax : 0422 - 2676016
Email : ceandct@dataone.in
ceandct@gmail.com
Website: www.annaimeenakshi.in

Requisition for Content Validity

Ref. No. From *Date :* .....

Mrs. Mary Geen
II - Year M.Sc(N)
Annai Meenakshi College of Nursing,
Coimbatore – 21.

Through
The Principal,
Annai Meenakshi College of Nursing,
Coimbatore – 21.

To

Respected Sir/Madam,

Sub: Requisition for expert opinion and suggestion for content validity of the tools – Reg.

I am a student of M.Sc., Nursing II year of Annai Meenakshi College of Nursing, Coimbatore, affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai. As a partial fulfillment of the M.Sc., Nursing programme. I am conducting a "A Study to Evaluate The Effectiveness of cold application at injection site on level of pain associated with Intra Muscular Immunization among infants in selected hospital at Coimbatore ".

I am hereby enclosing the following:

7. **Statement and objectives of the study**
8. **Hypothesis**
9. **Methodology**
10. **Tool**
11. **Intervention**
12. **Content Validity certificate.**

Herewith I am submitting the developed tool for content validity and for expert opinion and possible suggestion. It will be grateful to you and request you to return the same to the undersigned at the earliest possible.

Thanking you,

Yours faithfully,

Place: Coimbatore
Date:

16.3.15
PRINCIPAL
Annai Meenakshi College of Nursing
COIMBATORE-641 021.

APPENDIX B

Certificate Of Validation

ANNAI MEENAKSHI COLLEGE OF NURSING

Affiliated with the Tamil Nadu Dr. M.G.R Medical University, Chennai.
Approved by the Indian Nursing Council, New Delhi &
Tamil Nadu Nurses and Midwives Council, Chennai.

Madukkarai Market Road,
P.B. No. 4431
Industrial Estate Post,
COIMBATORE - 641 021.

0422 - 6562705
94421 75641
98435 24219

Phone : 0422 - 2675641, 2672705
Fax : 0422 - 2676016
Email : ceandct@dataone.in
ceandct@gmail.com
Website: www.annaimeenakshi.in

Ref. No.

Date : .....

Certificate of Validation

This is to certify that the tool submitted by **Mrs. Mary Geen.** M.Sc (N) II - Year student of Annai Meenakshi College of Nursing, Coimbatore, Tamil Nadu (Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai) is validated by undersigned and can proceed with this tool and conduct the dissertation entitled conducting **"A Study to Evaluate The Effectiveness of cold application at injection site on level of pain** associated with **Intra Muscular Immunization among infants in selected hospital at Ernakulam."**

Place: Coimbatore

Signature

Date:

Name and Designation

APPENDIX–C

Name List Of Experts Who Validated The Tool

Dr. JABEEL MOHAMMED, M.B.B.S., D.C.H.,

Chief Medical officer,

Taluk Hospital,

Ernakulam.

Dr. ABDUL SATHAR., M.B.B.S., D.C.H.,

Consultant Peadiatricain,

Taluk Hospital,

Ernakulam.

PROF. INDRANI, M.Sc(N).,

Professor,

Nightingale College of Nursing,

Coimbatore.

PROF.EMERENSIA, M.Sc(N).,

Professor,

R.V.S College of Nursing,

Sulur.

Mrs.RAJESWARI.Sc(N).,

Reader,

R.V.S. College of Nursing,

Sulur.

PROF.THENMOZHI, M.Sc(N).,

Professor,

Texicity College of Nursing,

Coimbatore.

Mrs. S. MEERA, M.Sc(N).,

Assisstant Professor,

Ellen College of Nursing,

Coimbatore.

APPENDIX-D

Letter Seeking And Granting Permission To Conduct Study

ANNAI MEENAKSHI COLLEGE OF NURSING

Affiliated with the Tamil Nadu Dr. M.G.R Medical University, Chennai.
Approved by the Indian Nursing Council, New Delhi &
Tamil Nadu Nurses and Midwives Council, Chennai.

Madukkarai Market Road,
P.B. No. 4431
Industrial Estate Post,
COIMBATORE - 641 021.

0422 - 6562705
94421 75641
98435 24219

Phone : 0422 - 2675641, 2672705
Fax : 0422 - 2676016
Email : ceandct@dataone.in
ceandct@gmail.com
Website: www.annaimeenakshi.in

Ref. No.

Date : .....

April 23, 2015

Mrs. Mary Geen
II year M.Sc.,(N)
Annai Meenakshi College of Nursing,
Coimbatore – 21.

To
Chief Medical Officer (THE SUPERINTENDENT)
Govt. Hospital,
Palluruthy,
Ernakulam.

Through Principal of Annai Meenakshi College of Nursing,

Respected Sir/Madam,

Sub: Conduct study – Permission – Request - Regarding

I am Mrs. Mary Geen. doing M.Sc., Nursing II year in Annai Meenakshi College of Nursing, Coimbatore. As a part of requirement given by The Tamilnadu Dr.M.G.R. Medical University, Chennai. I need to conduct **"A Study to Evaluate The Effectiveness of cold application at injection site on level of pain** associated with **Intra Muscular Immunization among infants in selected hospital at Ernakulam"**. Hence I request you to kindly permit me to collect data during the period of 06.05.2015 to 20.05.2015.

Thanking you

Yours faithfully,

Forwarded

PRINCIPAL
Annai Meenakshi College of Nursing
COIMBATORE-641 021.

SUPERINTENDENT
TALUK HOSPITAL
PALLURUTHY

TALUK HOSPITAL * PALLURUTHY, COCHIN - 9 *

ഭരണഭാഷ – മാതൃഭാഷ

എറണാകുളം ജില്ലാ മെഡിക്കൽ ഓഫീസറുടെ (ആരോഗ്യം) നടപടിക്രമം

വിഷയം:– ആരോഗ്യവകുപ്പ് – താലൂക്കാശുപത്രി പള്ളുരുത്തിയിൽ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവ് പുറപ്പെടുവിക്കുന്നു.

പരാമർശം:– കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് പ്രിൻസിപ്പാളിന്റെ 23/4/15-ലെ കത്ത്.

ഉത്തരവ് നം: സി4-11903/14/ജി.മെ.ഒ(ആ)/എറണാകുളം/തീയതി: 04/05/2015

കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് രണ്ടാം വർഷ എം.എസ്.സി വിദ്യാർത്ഥിനിയായ മിസ്സിസ്. മേരി ജീനിന്, അവരുടെ പഠന ആവശ്യത്തിനായി പള്ളുരുത്തി താലൂക്കാശുപത്രിയിൽ നിന്നും 06/05/15 മുതൽ 20/05/15 വരെ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവാകുന്നു.

(ഒപ്പ്)
ഡോ. ബീന.കെ.വി.
ജില്ലാ മെഡിക്കൽ ഓഫീസർ (ആരോഗ്യം),
എറണാകുളം.

മിസ്സിസ്. മേരി ജീൻ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ.

പകർപ്പ് :– 1) സൂപ്രണ്ട്,
താലൂക്കാശുപത്രി, പള്ളുരുത്തി.
2) പ്രിൻസിപ്പാൾ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ – 21.
3) സഞ്ജയം.

//ഉത്തരവിൻ പ്രകാരം //

സൂപ്രണ്ട്.

A/4.5.15

ഭരണഭാഷ – മാതൃഭാഷ

എറണാകുളം ജില്ലാ മെഡിക്കൽ ഓഫീസറുടെ (ആരോഗ്യം) നടപടിക്രമം

വിഷയം:– ആരോഗ്യവകുപ്പ് – താലൂക്കാശുപത്രി പളളുരുത്തിയിൽ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവ് പുറപ്പെടുവിക്കുന്നു.

പരാമർശം:– കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് പ്രിൻസിപ്പാളിന്റെ 23/4/15-ലെ കത്ത്.

ഉത്തരവ് നം: സി4–**11903/14**/ജി.മെ.ഒ(ആ)/എറണാകുളം/തീയതി: **04/05/2015**

കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് രണ്ടാം വർഷ എം.എസ്.സി വിദ്യാർത്ഥിനിയായ മിസ്സിസ്. മേരി ജീനിന്, അവരുടെ പഠന ആവശ്യത്തിനായി പളളുരുത്തി താലൂക്കാശുപത്രിയിൽ നിന്നും 06/05/15 മുതൽ 20/05/15 വരെ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവാകുന്നു.

(ഒപ്പ്)
ഡോ. ബീന.കെ.വി.
ജില്ലാ മെഡിക്കൽ ഓഫീസർ (ആരോഗ്യം),
എറണാകുളം.

മിസ്സിസ്. മേരി ജീൻ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ.

പകർപ്പ് :– 1) സൂപ്രണ്ട്,
താലൂക്കാശുപത്രി, പളളുരുത്തി.
2) പ്രിൻസിപ്പാൾ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ – 21.
3) സഞ്ജയം.

//ഉത്തരവിൻ പ്രകാരം //

സൂപ്രണ്ട്.

A/4.5.15

ഭരണഭാഷ – മാതൃഭാഷ

എറണാകുളം ജില്ലാ മെഡിക്കൽ ഓഫീസറുടെ (ആരോഗ്യം) നടപടിക്രമം

വിഷയം:- ആരോഗ്യവകുപ്പ് – താലൂക്കാശുപത്രി പളളുരുത്തിയിൽ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവ് പുറപ്പെടുവിക്കുന്നു.

പരാമർശം:- കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് പ്രിൻസിപ്പാളിന്റെ 23/4/15-ലെ കത്ത്.

ഉത്തരവ് നം: സി4-**11903/14/**ജി.മെ.ഒ(ആ)/എറണാകുളം/തീയതി: **04/05/2015**

കോയമ്പത്തൂർ അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ് രണ്ടാം വർഷ എം.എസ്.സി വിദ്യാർത്ഥിനിയായ മിസ്സിസ്. മേരി ജീനിന്, അവരുടെ പഠന ആവശ്യത്തിനായി പളളുരുത്തി താലൂക്കാശുപത്രിയിൽ നിന്നും 06/05/15 മുതൽ 20/05/15 വരെ ഡാറ്റ ശേഖരിക്കുന്നതിനായി അനുവാദം നൽകി ഉത്തരവാകുന്നു.

(ഒപ്പ്)
ഡോ. ബീന.കെ.വി.
ജില്ലാ മെഡിക്കൽ ഓഫീസർ (ആരോഗ്യം),
എറണാകുളം.

മിസ്സിസ്. മേരി ജീൻ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ.

പകർപ്പ് :- 1) സൂപ്രണ്ട്,
താലൂക്കാശുപത്രി, പളളുരുത്തി.
2) പ്രിൻസിപ്പാൾ,
അണ്ണാ മീനാക്ഷി കോളേജ് ഓഫ് നഴ്സിംഗ്,
കോയമ്പത്തൂർ – 21.
3) സഞ്ജയം.

//ഉത്തരവിൻ പ്രകാരം //

സൂപ്രണ്ട്.

A/4.5.15

APPENDIX E

Consent Form (English)

Respected Sir / Madam,

I am Mary Geen, I am doing my second year M.Sc., (N) in Annai Meenakshi College of Nursing. I am conducting a Research on "A study to evaluate the effectiveness of cold application on level of pain associated with intramuscular immunization among infants in selected hospital at Ernakulum." I request your co-operation to complete my research. I assure you that you won't get any harm due to this intervention.

I Mr. / Mrs. …… was explained about the effectiveness of cold application on level of pain associated with intramuscular immunization among infants by Mrs. Mary Geen. She explained me the benefits of this intervention. I agree with this intervention of cold application and this study project whole heartedly.

Yours faithfully,

Date :

Time :

APPENDIX F

Consent Form (Malayalam)

സത്യവാങ്ങ്മൂലം - ഇ

സമ്മതപത്രം

ബഹുമാനപ്പെട്ട മാഡം/ സർ,

എന്റെ പേര് മേരി ജീൻ എന്നാണ്. ഞാൻ അഞ്ജെന്ന മീനാക്ഷി നേഴ്സിംങ്ങ് കോളേജിൽ രണ്ടാം വർഷ എം.എസ്.സി (നേഴ്സിംങ്ങ്) വിദ്യാർത്ഥിനിയാണ്. ഞാൻ ഒരു വിഷയത്തിൽ റിസർച്ച് ചെയ്യുന്നുണ്ട്. ആ വിഷയം "എ സ്റ്റഡി ടു ഇവാലുവേറ്റ് ദി ഇഫറ്റീവ്നെസ്സ് ഓഫ് കോൾഡ് ആപ്ലിക്കേഷൻ അറ്റ് ഇൻജക്ഷൻ സെറ്റ് ഓൺ ലെവൽ ഓഫ് പെയിൻ ഡ്യൂറിംങ്ങ് ഇൻട്രാമസ്ക്കുലർ ഇമ്മ്യൂണൈസേഷൻ എമങ്ങ് ഇൻഫൻസ്."

എന്റെ റിസർച്ച് പൂർത്തീയാക്കുന്നതിനുവേണ്ടി എല്ലാവിധ സഹായവും സഹകരണവും ചെയ്ത് തരണമെന്ന് ഞാൻ അപേക്ഷിക്കുന്നു. എന്റെ റിസർച്ച് കൊണ്ട് യാതൊരു ബുദ്ധിമുട്ടും നിങ്ങൾക്ക് ഉണ്ടാകുന്നതല്ല എന്ന് ഞാൻ ഉറപ്പ് നൽകുന്നു.

ഞാൻ മിസ്റ്റർ/മിസിസ്സ് .....

റിസർച്ചിന്റെ വിഷയത്തെക്കുറിച്ചും അതിന്റെ നേട്ടങ്ങളെക്കുറിച്ച് വിശദീകരിക്കുകയും ചെയ്തു. ഞാൻ ഐസ് ആപ്ലിക്കേഷൻ എന്ന കണ്ടുപിടുത്തത്തെ അംഗീകരിക്കുകയും ആ വിഷയത്തെക്കുറിച്ച് പൂർണ്ണ മനസ്സോടെ പഠിക്കുകയും ചെയ്തു.

എന്ന്

വിശ്വസ്തയോടെ

തിയതി :

സമയം :

APPENDIX G

Structured Questionnaire (English)

SELF ADMINISTERED QUESTIONNAIRE ON DEMOGRAPHIC VARIABLES

INSTRUCTION: Sample No.60

1. Read thoroughly section A.

2. It contains question regarding demographic variables. Please put tick mark (√) in appropriate space

1)Age

a) 1.5 – 2.5 months

b) 2.5 – 3.5 months

c) 3.5 – 4.5 months

2) Sex

a) Male

b) Female

3) Weight

a) 2 – 4 kg

b) 5 – 7 kg

c) 8 – 10 kg

4) Position of child during injection

a) Sitting (holding with parents)

b) Lying

5) Order of vaccine

a) Penta1

b) Penta2

c) Penta3

6) Previous experience of cold application

a) Yes

b) No

7) Previous experience of Intra Muscular injection

a) Yes

b) No

8) History of allergic reaction due to intramuscular injection previously

a) Yes

b) No

If yes specify

APPENDIX – H

Structured Questionnaire (Malayalam)

അനുബന്ധം –എഫ്

ജനസംഖ്യശാസ്ത്രത്തെക്കുറിച്ചുള്ള സ്വയംഭരണ ചോദ്യാവലി

നിർദ്ദേശങ്ങൾ:

1. സെക്ഷൻ എ സൂക്ഷ്മമായി വായിക്കുക
2. ജനസംഖ്യശാസ്ത്രത്തെക്കുറിച്ചുള്ള ചോദ്യങ്ങളാണ് ഉൾപ്പെടിത്തിരിക്കുന്നത്.

   ശരിയായ ഉത്തരത്തിന് നേരെ √ അടയാളപ്പെടുത്തുക.

   1. വയസ്സ്

      എ) 1.5 – 2.5 മാസം

      ബി) 2.5 – 3.5 മാസം

      സി 3.5 – 4.5 മാസം

   2. ലിംഗം

      എ) ആൺ

      ബി) പെൺ

   3. ഭാരം

      എ) 2–4 കിലോ

      ബി) 5–7 കിലോ

      സി) 8–10 കിലോ

4. കുത്തിവെയ്പ് നടത്തുമ്പോൾ കുട്ടിയുടെ നില

   എ) ഇരിക്കുന്നു (രക്ഷിതാക്കളുടെ കൂടെ)

   ബി) കിടക്കുന്നു

5. വാക്സിന്റെ ക്രമം

   എ) പെന്റാ 1

   ബി) പെന്റാ 2

   സി) പെന്റാ 3

6. ഐസ് ആപ്ലിക്കേഷന്റെ മുൻ പരിചയം

   എ) അതെ

   ബി) അല്ല

7. ഐ എം കുത്തിവെയ്പിന്റെ മുൻ പരിചയം

   എ) അതെ

   ബി) അല്ല

8. മുൻപ് കുത്തിവെയ്പിന് എന്തെങ്കിലും പ്രതികരണം സംഭവിച്ചിട്ടുേ ാ?

   എ) അതെ

   ബി) അല്ല

   അതെ ആണെങ്കിൽ വിവരിക്കുക

APPENDIX I

Standardized Neonatal Infant Pain Scale (English)

NEONATAL INFANT PAIN SCALE		
PARAMETER	FINDING	POINTS
Facial Expression	Relaxed	0
	Grimace	1
Cry	No cry	0
	Whimper	1
	Vigorous crying	2
Breathing Patterns	Relaxed	0
	Change in breathing	1
Arms	Restrained	0
	Relaxed	0
	Flexed	1
	Extended	1
Legs	Retrained	0
	Relaxed	0
	Flexed	1
	Extended	1
State of Arousal	Sleeping	0
	Awake	0
	Fussy	1

APPENDIX J

Neonatal Infant Pain Scale (Malayalam)

സ്റ്റാന്റ്ഡേർഡ് നിയോനാറ്റൽ ഇൻഫന്റ് പെയിൻ സ്കെയിൽ

നിയോനാറ്റൽ ഇൻഫന്റ് പെയിൻ സ്കെയിൽ

സ്വാഭാവവിശേഷങ്ങൾ	കണ്ടുപിടുത്തങ്ങൾ	നില
മുഖഭാവങ്ങൾ	സ്വസ്ഥതയുള്ള	0
	കൃത്രിമനോട്ടം	1
കരച്ചിൽ	കരയാതിരിക്കുന്നത്	0
	തേങ്ങുക	1
	അതിശക്തമായ കരച്ചിൽ	2
ശ്വാസഗതികൾ	സ്വസ്ഥതയുള്ള	2
	വ്യത്യാസമുള്ള ശ്വസനം	0
കൈകൾ	സ്വസ്ഥതയുള്ള	0
	നിയന്ത്രിച്ച	0
	മടക്കുക	1
	നീട്ടുക	1
സ്റ്റേറ്റ് ഓഫ് അറോസൽ	ഉറങ്ങുക	0
	ഉണർന്നിരിക്കുക	0
	ബഹളം കൂട്ടുക	1

APPENDIX – K

Scoring Key

Regarding pain score, the maximum score is 7 and minimum score is 0. The score was divided into the following categories.

0 - 1	:	No pain
2 - 3	:	Mild pain
4 - 5	:	Moderate pain
6 - 7	:	Severe

APPENDIX – L

Cold Application Procedure

Definition:

Cold application is defined as applying ice or cold to an injury for a therapeutic effect.

Purpose:

- To alleviate the Pain
- To improve superficial vasodilatation
- To bring about relaxation of muscle
- To reduce needle anxiety
- To give anesthetic effect

Mechanisms of COLD APPLICTION on reducing pain

The mechanism of cold application is GATE CONTROL THEORY. In Cold application while applying ice before intramuscular injection the nervous system will shut down the sensory gate and the pain sensation of the injection will not reach the brain. So the injection pain goes unnoticed.

According Ronald Melzack and Patrick Wall (1965) the nerve fibers with smaller diameter carry pain stimuli through the gate mechanism present in spinal cord. But, the nerve fibers with larger diameter, which carry other stimuli such as touch, pass through

the same gate. The larger nerves inhibit the transmission of pain signals by smaller nerves through the gate.

When the pain sensation is produced in any part of the body, along with pain fibers, the other afferents particularly the touch fibers reaching the posterior column of spinal cord are activated. The posterior column fibers send collaterals to the cells of substantia gelatinosa in the posterior gray horn. Thus, some of the impulses ascending via dorsal column fibers pass through the collaterals and reach substantia gelatinosa. Here, touch impulses inhibit the release of substance by the pain fibers ending on substantia gelatinosa, so the pain sensation is suppressed. Some of the possible mechanisms include

1. Decreases the amount of bleeding by vasoconstriction into the injury site and so lessens swelling
2. A decreased nerve transmission in pain fibres
3. Cold reduces the activity of free nerve endings
4. Cold raises the pain threshold
5. Cold causes a release of endorphins

Indications of Cold application

- It reduces the procedural pain.
- It relaxes muscle.

ARTICLES

S.NO.	ARTICLES	PURPOSES
1	Clean tray containing Syringe and needles of appropriate size.	To administer the injection.
2	Sterile cotton swabs and gauze pieces in sterile containers.	To clean the skin at the site of injection.
3	Methylated spirit in a container.	To clean the skin.
4	Kidney tray and paper bag.	To receive the waste.
6	Drug ordered.	
8	Small covered tray (sterile)	To carry the prepared injections to the bedside.

PROCEDURE

S.NO.	STEPS	RATIONALE
1	Patients should be identified as per inclusion criteria.	To get the correct samples.
2	The details of the study and need for the study will be explained to the parent and obtain the written consent.	To win his/her confidence and cooperation.
3	Check the clients' identification and condition.	To assess sufficient condition on the client.

4	Explain to the client about the purpose and the procedure.	Providing information fosters co-operation.
5	Screen the patient.	To protect the clients privacy.
6	Placing the appropriate position. 1) Move the client to sitting position or lying position with mother support 2) Spread the mackintosh under the client's body.	To make him / her comfortable and provide the care easily. To avoid soiling of the linen.
7	Identifying the injection site (vastus lateralis site of thigh)	To administer the medication correctly.
8	Give cold application (at the injection site) for approximately 5seconds	To relax the muscle and to get an anesthetic feel or not feel pain at time of injection

S.NO.	STEPS	RATIONALE
9	Wipe the skin with spirit and dry thoroughly.	To prevent cross infection.
10	Uncap the syringe and To locate injection site, make an imaginary box on the upper leg. Find the groin one hand's width below the groin becomes the upper border of the box.	To identify the correct injection site.

	Find the top of knee. One hand's widths above the top of the knee become the lower border of the box and insert the needle with medicine at right angle to the site.	
11	Remove the needle quickly	To alleviate the pain.
12	Pain assessment will be done by using Standardized neonatal infant pain scale.	To identify the level of pain perception
13	Wash hands.	To limit transfer of micro organisms

AFTER CARE

- Make the patient comfortable.
- Remove screen and equipment.
- Inspect the area for bleeding.
- Watch the signs and symptoms of allergic reaction.
- Clean articles with soap and water keep ready for next use.

APPENDIX – M

Photos